

=====
 Bp number: 01-024-20n
 =====

App number: 2001-248XRAB Begin movement: 2/21/01
 Received: 1/24/01 End movement: 2/21/02
 Institution: Monsanto Begin release: 2/21/01
 Recipient: Wheat End release: 2/21/02
 Status: Pending Acre: 40.00
 Effective date: 2/23/01 CBI status: CBI

Phenotype: HT - Glyphosate tolerant

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax:

636-737-7085

(b) (6), (b) (7)(C)

1. Assign Bp number and initial data entry

Initial

[apd]

Date

[1/25/01]

Initial Data Entry

2. Review by biotechnologist

[RER]*

JAN 29 2001

3. Letter of notification to State

Fed-ex

[KLN]

[1/30/01]*

4. State response

O/d	Loc	Site	Reg	Initial	Date
Interstate	*Dest*HI	*	*WR *	[]	[]
Interstate	*Dest*KS	*	*SCR *	[]	[]
Interstate	*Dest*MO	*	*SCR *	[]	[]
Interstate	*Dest*SD	*	*SCR *	[]	[]
Interstate	*Orig*HI	*	*WR *	[]	[]
Interstate	*Orig*KS	*	*SCR *	[]	[]
Interstate	*Orig*MO	*	*SCR *	[]	[]
Interstate	*Orig*SD	*	*SCR *	[]	[]
Release	*	*SD	* 2*SCR *	[]	[]

5. Enter genes into database

[apd]

[1/29/01]

6. Letter of acknowledgement/denial/withdraw

[KLN]

[2/23/01]*

7. Enter final data into database

[KLN]

[2/28/01]

8. If deny, reason: Address incomplete, Signature mismatch,
 Ph category, Phenotype, Gene, Donor, Marker,
 Does not qualify

**CONFIDENTIAL****Monsanto Reference ID**

2001-248XRAB

Permit Unit

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

January 22, 2001

USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

01-024-20n

1. USDA Reference Number**2. Applicant Reference Number** 2001-248XRAB**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)
FAX 636/737-7085
EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release February 21, 2001 - February 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Oxen, Ingot

CONFIDENTIAL

Monsanto Reference ID

2001-248XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [REDACTED]

(b)(4)

CBI

[REDACTED]
(b)(4)

Gene: CTP2-CP4-- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3'-- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [REDACTED]

(b)(4)

CBI

[REDACTED]
(b)(4)

Gene: CTP2-CP4-- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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CONFIDENTIAL

Monsanto Reference ID

2001-248XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 50,000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, SD

DESTINATION:

HI, KS, MO, SD

Ship From:**HI***[redacted] (b)(4) [redacted] Honolulu
County/Province, HI, (b)(4) U.S.A.CONTACT: [redacted] (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI [redacted] U.S.A. (b) (4), (b) (6), (b) (7)(C)
] - CBI**KS***[redacted] (b)(4) Sedgwick County/Province, KS, (b)(4) USA
CONTACT: [redacted] (b) (4), (b) (6), (b) (7)(C) KS, [redacted] USA,
(b) (4), (b) (6), (b) (7)(C)
] - CBI**MO***[redacted] (b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.
CONTACT: [redacted] (b) (4), (b) (6), (b) (7)(C) MO, [redacted]
U.S.A., (b) (4), (b) (6), (b) (7)(C)
] - CBI**SD***[redacted] (b)(4) Brookings
County/Province, SD, (b)(4) USA

CONFIDENTIAL

Monsanto Reference ID

2001-248XRAB

CONTACT: Jackie Rudd, South Dakota State University, NPB 248C, Box 2140-C, Brookings, SD, 57007, U.S.A., 605/688-4769

] - CBI

Ship To:**HI**

*[(b)(4) Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

KS

*[(b)(4) Sedgwick County/Province, KS, (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.
CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-248XRAB

SD

*[REDACTED] (b)(4) Brookings
County/Province, SD (b)(4) USA

CONTACT [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] SD,
(b) (4), (b) (6), (b) (7)(C) U.S.A., [REDACTED]

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-248XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (2)

SD

[REDACTED] (b)(4) Brookings County/Province, SD, USA, 20
acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b)(4)

Codington
County/Province, SD, USA, 20 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

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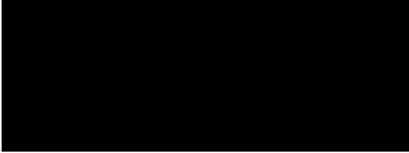
Monsanto Reference ID

2001-248XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 22, 2001

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" if("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

Monsanto Reference ID

2001-248XRAB

Permit Unit

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

January 22, 2001

USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

01-024-20n

1. USDA Reference Number

2. Applicant Reference Number 2001-248XRAB

3. Applicant/Responsible Party

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Phone

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FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North
St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release

February 21, 2001 - February 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Oxen, Ingot

CBI-DELETED

Monsanto Reference ID

2001-248XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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CBI-DELETED

Monsanto Reference ID

2001-248XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 50,000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, SD

DESTINATION:

HI, KS, MO, SD

Ship From:**HI**[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.**KS**[CBI Deleted] -- *Sedgwick County/Province, KS, USA**MO**[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.**SD**[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID

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Ship To:

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[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

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MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID

2001-248XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

SD (2)

SD

[CBI Deleted] -- Brookings County/Province, SD, USA, 20 acres

[CBI Deleted] -- Codington County/Province, SD, USA, 20 acres

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CBI-DELETED

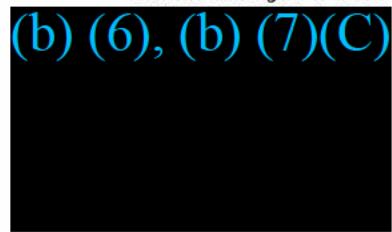
Monsanto Reference ID

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9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 22, 2001

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St. Louis

MO

63198

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GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

*CBI**No Marker gene*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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8. Introduction Interstate Movement and Release

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DESTINATION:

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Ship From:

HI

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MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID

2001-248XRAB

Ship To:**HI**

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

SD

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CBI-DELETED

Monsanto Reference ID

2001-248XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD (2)

SD

[CBI Deleted] -- Brookings County/Province, SD, USA, 20 acres

[CBI Deleted] -- Codington County/Province, SD, USA, 20 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

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January 22, 2001

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700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 25, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-024-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-20n Applicant #: 2001-248XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO SD
Release destination: SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JSI

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007792

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 25, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-024-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-20n Applicant #: 2001-248XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO SD
Release destination: SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|SJ|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007793

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 25, 2001

Dear Mr. Brown:

Enclosed is notification 01-024-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-20n Applicant #: 2001-248XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO SD
Release destination: SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|SJ|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007794

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

January 25, 2001

Dear Mr. Fridley:

Enclosed is notification 01-024-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-024-20n	Applicant #:	2001-248XRAB
Received:	January 24, 2001	Effective:	February 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: HI KS MO SD			
Release destination: SD			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007795



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

January 25, 2001

Dear Mr. Fridley:

Enclosed is notification 01-024-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

By number	01-024-20n	Applicant #:	2001-248XRB
Received:	January 24, 2001	Effective:	February 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: HI KS MO SD			
Release destination: SD			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Kevin Fridley

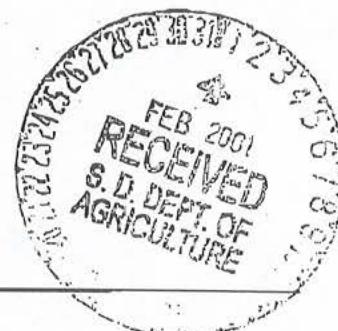
Signature:

(b) (6), (b) (7)(C)

Date: 2/1/01

State: South Dakota

Rptloc01/R4



FEB 5 2001



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OR120018_BR_007796



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 25, 2001

Dear Mr. Brown:

Enclosed is notification 01-024-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-20n Applicant #: 2001-248XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO SD
Release destination: SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

Y State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael B. Brown

Signature: _____ (b) (6), (b) (7)(C) _____

Date: 2/2/01

State: MD

Rptloc01/R4

FEB 5 2001



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We Equal Opportunity Employer



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 25, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-024-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-20n Applicant #: 2001-248XRAB
 Received: January 24, 2001 Effective: February 23, 2001
 Institution: Monsanto Recipient: Wheat
 Interstate destination: HI KS MO SD
 Release destination: SD

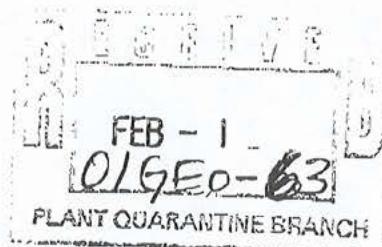
Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine



Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

(b) (6), (b) (7)(C)

Signature: _____

Date: 22 February 2001

State: Hawaii

Rptloc01/R4



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FEB 23 2001

OR120018_BR_007798

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 23, 2001.

Interstate movement and Release
Notification no. 01-024-20n (2001-248XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

OR120018_BR_007799

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept of Agric., Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric., Pierre, SE
R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-024-20n

MODE = MEMORY TRANSMISSION

START=FEB-27 10:28

END=FEB-27 10:34

FILE NO.=522

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK	2	916367377085	004/004	00:05:38

***** -

- ***** -

- *****



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to
7 CFR 340.3(c), effective on or after February 23, 2001.

Interstate movement and Release
Notification no. 01-024-23n (2001-252XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure



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OR120018_BR_007801

CONFIDENTIAL

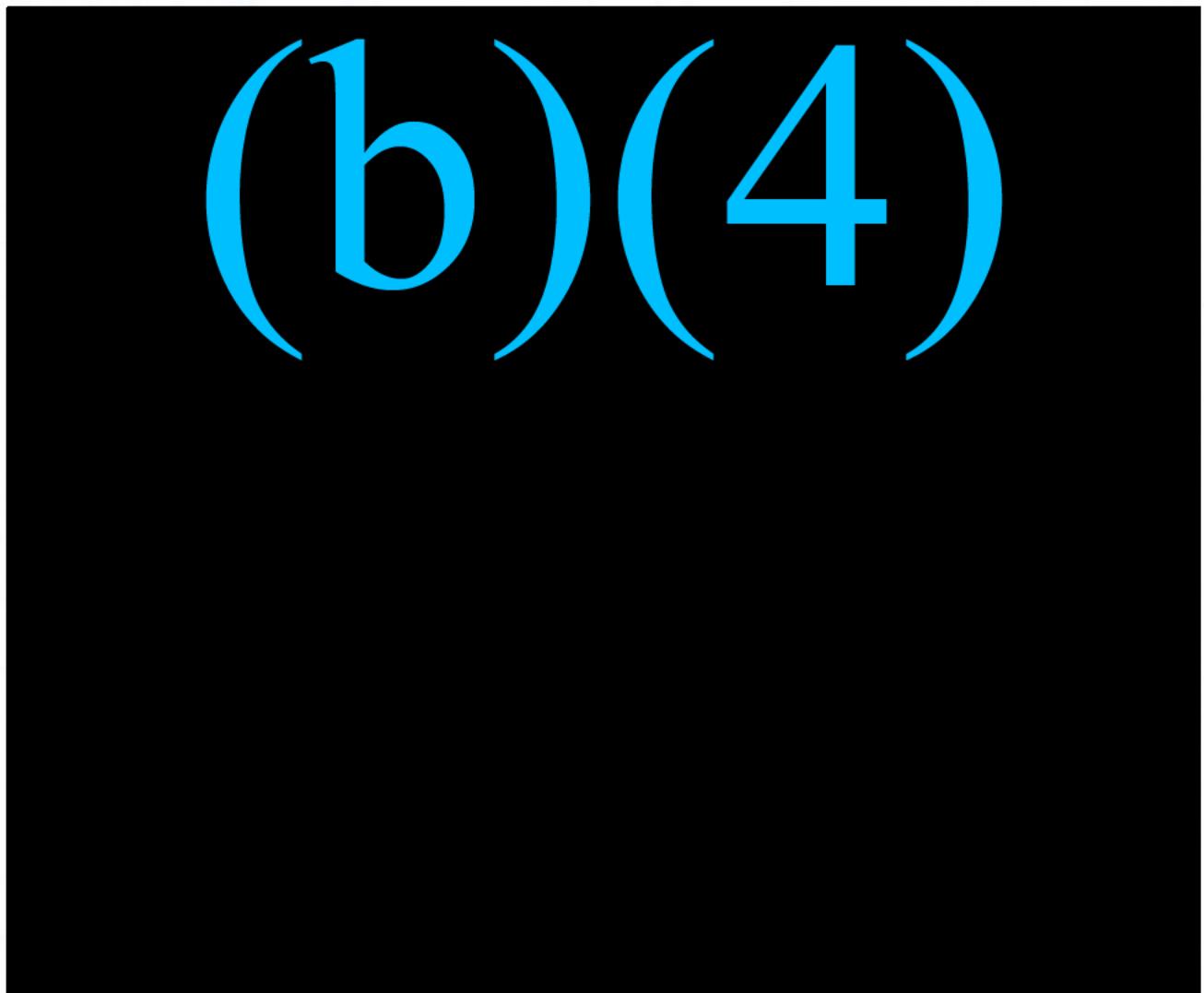
**2001 Wheat Field Test Report
USDA #01-024-20n Monsanto #2001-248XRAB**

October 16, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147307538	Brookings County	SD
2147303325	Codington County	SD

Brookings County/SD (2147307538)



(b)(4)

Codington County/SD (2147303325)

(b)(4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. ILS, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-024-20n Monsanto #2001-248XRAB**

October 16, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147307538	Brookings County	SD
2147303325	Codington County	SD

Brookings County/SD (2147307538)

Planting Date: 05/11/2001

Harvest Date: 08/23/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Codington County/SD (2147303325)

Planting Date: 05/30/2001

Harvest Date: 09/13/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

=====
 Bp number: 01-024-21n
 =====

App number: 2001-249XRAB Begin movement: 2/21/01
 Received: 1/24/01 End movement: 2/21/02
 Institution: Monsanto Begin release: 2/21/01
 Recipient: Wheat End release: 2/21/02
 Status: Pending Acre: 10.00
 Effective date: 2/23/01 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: [REDACTED] (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[apd]	[1/25/01]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[RZR]*	JAN 29 2001
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KLnD]	[1/30/01]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg	[]	[]	
Interstate	*Dest*HI	*	*WR *	[]	[]	
Interstate	*Dest*KS	*	*SCR *	[]	[]	
Interstate	*Dest*MO	*	*SCR *	[]	[]	
Interstate	*Dest*MT	*	*WR *	[]	[]	
Interstate	*Orig*HI	*	*WR *	[]	[]	
Interstate	*Orig*KS	*	*SCR *	[]	[]	
Interstate	*Orig*MO	*	*SCR *	[]	[]	
Interstate	*Orig*MT	*	*WR *	[]	[]	
Release	*	*MT	* 1*WR *	[]	[]	
5.	<input checked="" type="checkbox"/> Enter genes into database				[apd]	[1/29/01]
6.	<input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw				[KLnD]	[2/23/01]*
7.	<input checked="" type="checkbox"/> Enter final data into database				[KLnD]	[2/28/01]
8.	<input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify					

Inclde Hawaii

MONSANTO

Food • Health • Hope



CONFIDENTIAL

Monsanto Reference ID

2001-249XRAB

Permit Unit

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

January 22, 2001

USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

01-024-21n

1. USDA Reference Number

2. Applicant Reference Number 2001-249XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release

February 21, 2001 - February 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety McNeal, Scholar

CONFIDENTIAL

Monsanto Reference ID

2001-249XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [REDACTED]

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4-- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3'-- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [REDACTED]

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4-- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3'-- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-249XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 50, 000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, MT

DESTINATION:

HI, KS, MO, MT

Ship From:**HI***[redacted] (b)(4) Honolulu
County/Province, HI, (b)(4), U.S.A.CONTACT: [redacted] (b) (4), (b) (6), (b) (7)(C)
[redacted] HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)
] - CBI**KS***[redacted] (b)(4) Sedgwick County/Province, KS, (b)(4) USA
CONTACT: [redacted] (b) (4), (b) (6), (b) (7)(C) KS, (b) (4) USA,
(b) (4), (b) (6), (b) (7)(C)
] - CBI**MO***[redacted] (b)(4) St. Louis County/Province, MO (b)(4)
U.S.A.
CONTACT: [redacted] (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
U.S.A. [redacted] (b) (4), (b) (6), (b) (7)(C)
] - CBI**MT***[redacted] (b)(4)
Gallatin County/Province, MT (b)(4) USA

CONFIDENTIAL

Monsanto Reference ID

2001-249XRAB

CONTACT: Bill Grey, Montana State University, Dept. of Plant Science and Plant Pathology, 214 AgBioscience Facility, Bozeman, MT, 59717-3150, USA

] - CBI

Ship To:**HI**

*[(b)(4) Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) HI (b)(4), (b) (6), (b) (7)(C) (b)(4), (b) (6), (b) (7)(C)

] - CBI

KS

*[(b)(4) Sedgwick County/Province, KS (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) KS (b)(4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.
CONTACT: (b)(4), (b)(6), (b)(7)(C) (b)(4), (b)(6), (b)(7)(C) MO, (b)(4), (b)(6), (b)(7)(C)
U.S.A.

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-249XRAB

MT

*[REDACTED] (b)(4)
Gallatin County/Province, MT (b)(4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-249XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

(b)(4)

Gallatin County/Province, MT, USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MT, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

MONSANTO

Food • Health • Hope



CONFIDENTIAL

Monsanto Reference ID

2001-249XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 22, 2001

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

**NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND
EXPRESSED TRAITS**

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

**CBI-DELETED****Monsanto Reference ID**

2001-249XRAB

Permit Unit

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

January 22, 2001

USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

01-024-21n

- 1. USDA Reference Number** 01-024-21n
- 2. Applicant Reference Number** 2001-249XRAB
- 3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone **(b) (6), (b) (7)(C)**
FAX 636/737-7085
EMail **(b) (6), (b) (7)(C)**@monsanto.com

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release February 21, 2001 - February 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety McNeal, Scholar

CBI-DELETED

Monsanto Reference ID

2001-249XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-249XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 50, 000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, MT

DESTINATION:

HI, KS, MO, MT

Ship From:**HI**

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-249XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

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[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-249XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

[CBI Deleted] -- Gallatin County/Province, MT, USA, 10 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID

2001-249XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 22, 2001

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (314) 737-7085

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MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID

2001-249XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

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January 22, 2001

01-024-21n

1. USDA Reference Number

2. Applicant Reference Number 2001-249XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 21, 2001 - February 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety McNeal, Scholar

CBI-DELETED

Monsanto Reference ID

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Monsanto Reference ID

2001-249XRAB

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ORIGIN:

HI, KS, MO, MT

DESTINATION:

HI, KS, MO, MT

Ship From:**HI**[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.**KS**[CBI Deleted] -- *Sedgwick County/Province, KS, USA**MO**[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.**MT**[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-249XRAB

Ship To:**HI**

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-249XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

[CBI Deleted] -- Gallatin County/Province, MT, USA, 10 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

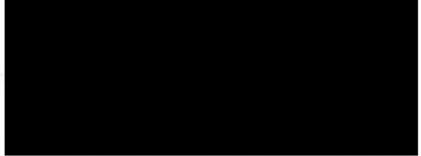
Monsanto Reference ID

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(b) (6), (b) (7)(C)



Monsanto Company

January 22, 2001

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700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

. file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 25, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-024-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-21n Applicant #: 2001-249XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO MT
Release destination: MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

lsl

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007832

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 25, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-024-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-21n Applicant #: 2001-249XRAB
Received: January 24, 2001 Effective: February 23, 2001
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Sincerely,

[SJ]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007833

.file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 25, 2001

Dear Mr. Brown:

Enclosed is notification 01-024-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

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Sincerely,

[S]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007834

file copy

Ms. Mary Bryson, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 25, 2001

Dear Ms. Bryson:

Enclosed is notification 01-024-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-21n Applicant #: 2001-249XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO MT
Release destination: MT

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Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007835



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 25, 2001

Dear Mr. Brown:

Enclosed is notification 01-024-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-21n Applicant #: 2001-249XRAB
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(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

Y State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/2/01

State: MO

Rptloc01/R4

FEB 5 2001



APHIS - Protecting American Agriculture

3147510005 P.08/19

OR120018_BR_007838

an Equal Opportunity Employer



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 25, 2001

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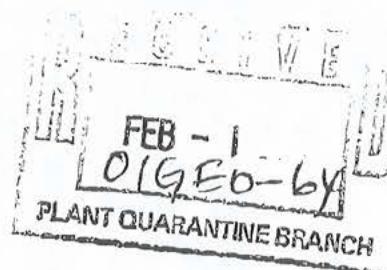
Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA



STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 22 February 2001

State: Hawaii

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 23 2001

OR120018_BR_007837



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Ms. Mary Bryson, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 25, 2001

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It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2-2-01

State: Montana

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_007838

FEB 2 2001

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 23, 2001.

Interstate movement and Release
Notification no. 01-024-21n (2001-249XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept of Agric., Jefferson City, MO
L. Witham, Montana Dept. of Agric., Helena, MT
R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-024-21n

OR120018_BR_007839

MODE = MEMORY TRANSMISSION

START=FEB-27 16:00 END=FEB-27 16:26

FILE NO.=528

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK	2	916367377085	011/011	00:25:21

***** - * * * * * - - * * * * *



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

February 27, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 28, 2001.

Interstate movement and Release
Notification no. 01-029-12n (2001-132XRAB)
Regulated article - Alfalfa
Destinations - California, Iowa, Idaho, Illinois, New York, Washington, Wisconsin

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

Please provide the Iowa Department of Agriculture with full information on the release site.

In addition, the State of Washington concurs with APHIS determination; however, you must comply with Washington's Quarantine for Japanese Beetle and Purple Nutsedge (see attached).

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

OO

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

CC:

B. Hass, California Dept. of Food and Agric., Sacramento, CA
C. Stoltenow, Iowa Dept. of Agric. and Land Stewardship, Des Moines, IA
R. Vega, Idaho Dept. of Agric., Boise, ID
S. Smith, Illinois Dept. of Agric., Des Plaines, IL



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OR120018_BR_007840

MODE = MEMORY TRANSMISSION

START=FEB-27 16:26 END=FEB-27 16:29

FILE NO.=529

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK	2	916367377085	001/001	00:01:59



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

(b) (6), (b) (7)(C)
Dear [REDACTED]

Your notification request has been acknowledged and may be executed according to
7 CFR 340.3(c), effective on or after February 23, 2001.

Interstate movement and Release
Notification no. 01-024-21n (2001-249XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c).
You or any of your cooperators who will be involved in handling the regulated
article must be prepared with a written or verbal description of the methods to
be employed to meet each performance standard. All packages must be clearly
labeled as to content, and notification number must be prominently displayed on
package.

This acknowledgment does not authorize use of "challenge organisms" for field
test.

In addition, the State of Hawaii has requested that you adhere to the following
requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department
of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon
arrival.

A copy of this letter of acknowledgment will be sent to the receiving State
Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:
M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept of Agric., Jefferson City, MO
L. Witham, Montana Dept. of Agric., Helena, MT
R. Stoaks, PPQ, WR, SCR, Sacramento, CA



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_007841

NO CBI

2001 Wheat Field Test Report
USDA #01-024-21n Monsanto #2001-249XRAB

October 16, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>	
2147307561	Gallatin County	MT	Not Planted

=====
 Bp number: 01-024-22n
 =====

App number: 2001-250XRAB Begin movement: 2/21/01
 Received: 1/24/01 End movement: 2/21/02
 Institution: Monsanto Begin release: 2/21/01
 Recipient: Wheat End release: 2/21/02
 Status: Pending Acre: 7.00
 Effective date: 2/23/01 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: [REDACTED] (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

		Initial	Date
1.	[<input checked="" type="checkbox"/> Assign Bp number and initial data entry	[apd]	[1/25/01]
2.	[<input checked="" type="checkbox"/> Review by biotechnologist	[KLR]*	JAN 29 2001
3.	[<input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KLR]	[1/30/01]*
4.	[<input type="checkbox"/> State response		

O/d	Loc	Site	Reg			
Interstate	*Dest*HI	*	*WR *	[]	[]	
Interstate	*Dest*KS	*	*SCR *	[]	[]	
Interstate	*Dest*MN	*	*NER *	[]	[]	
Interstate	*Dest*MO	*	*SCR *	[]	[]	
Interstate	*Orig*HI	*	*WR *			
Interstate	*Orig*KS	*	*SCR *			
Interstate	*Orig*MN	*	*NER *			
Interstate	*Orig*MO	*	*SCR *			
Release	*	*MN	* 1*NER *	[]	[]	
5.	[<input checked="" type="checkbox"/> Enter genes into database	[apd]	[1/29/01]			
6.	[<input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw	[KLR]	[2/28/01]*			
7.	[<input checked="" type="checkbox"/> Enter final data into database	[KLR]	[3/5/01]			
8.	[<input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify					

Reason for tardiness: (KS) did not respond

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-250XRAB

Permit Unit

January 22, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-024-22n

1. USDA Reference Number

2. Applicant Reference Number 2001-250XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release

February 21, 2001 - February 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety HJ98

CONFIDENTIAL

Monsanto Reference ID

2001-250XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [REDACTED]

(b) (4)

CBI

Gene: CTP2-CP4-- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3'-- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [REDACTED]

(b) (4)

CBI

Gene: CTP2-CP4-- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3'-- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-250XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 30,000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MN, MO

DESTINATION:

HI, KS, MN, MO

Ship From:**HI**

*[(b) (4)] County/Province, HI (b) (4) U.S.A. Honolulu

CONTACT: Robert Osgood, Hawaii Agriculture Research Center, 99-193 Aiea Heights Dr., Suite 300, Aiea, Oahu, HI, 96701-3911, U.S.A., 808/486-5348

] - CBI

KS

*[(b) (4)] Sedgwick County/Province, KS (b) (4) USA

CONTACT: Jerry Wilson, Monsanto Company, 5912 N. Meridian, Wichita, KS, 67204, USA, 316/755-7760

] - CBI

MN

*[(b) (4)] Ramsey County/Province, MN (b) (4) USA

CONTACT: Jim Anderson, University of Minnesota, 411 Borlaug Hall, 1991 Buford Circle, St. Paul, MN, 55108, U.S.A., 612/625-9763

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-250XRAB

MO

*[(b) (4)] St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] MO, e^{(b) (4), (b) (6), (b) (7)}
U.S.A. [(b) (4), (b) (6), (b) (7)(C)] - CBI

Ship To:

HI

*[(b) (4)] Honolulu
County/Province, HI, (b) (4) U.S.A.

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] HI [(b) (4), (b) (6), (b) (7)(C)] U.S.A. [(b) (4), (b) (6), (b) (7)(C)]

] - CBI

KS

*[(b) (4)] Sedgwick County/Province, KS (b) (4) USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] KS [(b) (4), (b) (6), (b) (7)(C)] USA,

] - CBI

MN

*[(b) (4)] Ramsey County/Province, MN (b) (4) USA

CONFIDENTIAL

Monsanto Reference ID

2001-250XRAB

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
MN, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO
* [REDACTED] (b) (4) St. Louis County/Province, MO (b) (4)
U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] (b) (4),
U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C) MO,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-250XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1)

MN

(b) (4)

Dakota

County/Province, MN, U.S.A., 7 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN, 55108, U.S.A. (b) (4), (b) (6), (b) (7)(C)

Comments: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) - CBI

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-250XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 22, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



CBI-DELETED

Monsanto Reference ID

2001-250XRAB

Permit Unit

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

January 22, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-024-22n

1. USDA Reference Number

2. Applicant Reference Number 2001-250XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 21, 2001 - February 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety HJ98

CBI-DELETED

Monsanto Reference ID

2001-250XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-250XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 30,000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MN, MO

DESTINATION:

HI, KS, MN, MO

Ship From:**HI**

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-250XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-250XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1)

MN

[CBI Deleted] -- Dakota County/Province, MN, U.S.A., 7 acres

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Food • Health • Hope



CBI-DELETED

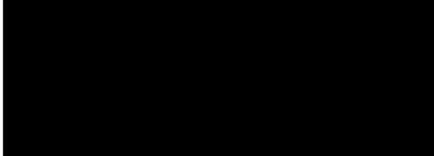
Monsanto Reference ID

2001-250XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 22, 2001

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

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CBI-DELETED

Monsanto Reference ID

2001-250XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-024-22n

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

January 22, 2001

1. USDA Reference Number

2. Applicant Reference Number 2001-250XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 21, 2001 - February 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety HJ98

CBI-DELETED

Monsanto Reference ID

2001-250XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

No marker

CBI-DELETED

Monsanto Reference ID

2001-250XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 30,000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MN, MO

DESTINATION:

HI, KS, MN, MO

Ship From:**HI**[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.**KS**[CBI Deleted] -- *Sedgwick County/Province, KS, USA**MN**[CBI Deleted] -- *Ramsey County/Province, MN, USA**MO**[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-250XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Ramsey County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-250XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1)

MN

[CBI Deleted] -- Dakota County/Province, MN, U.S.A., 7 acres

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CBI-DELETED

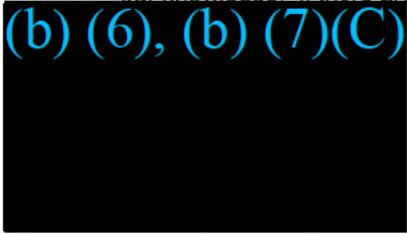
Monsanto Reference ID

2001-250XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Company

January 22, 2001

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 25, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-024-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-22n Applicant #: 2001-250XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MN MO
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(SJ)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007867

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 25, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-024-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-22n Applicant #: 2001-250XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MN MO
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|SJ|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007868

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 25, 2001

Dear Dr. Hanks:

Enclosed is notification 01-024-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-22n Applicant #: 2001-250XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MN MO
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007869

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 25, 2001

Dear Mr. Brown:

Enclosed is notification 01-024-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-22n Applicant #: 2001-250XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MN MO
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|SJ|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007870



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 25, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-024-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-22n Applicant #: 2001-250XRAB
 Received: January 24, 2001 Effective: February 23, 2001
 Institution: Monsanto Recipient: Wheat
 Interstate destination: HI KS MN MO
 Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.

 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

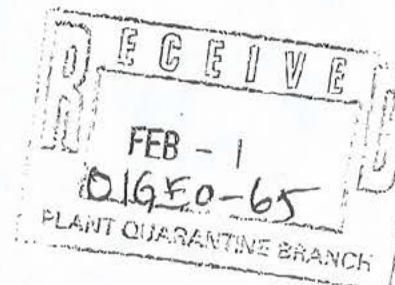
Signature: _____

(b) (6), (b) (7)(C)

Date: 22 February 2001

State: Hawaii

Rptloc01/R4



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An Equal Opportunity Employer

FEB 23 2001

OR120018_BR_007871



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

faxed 3-1-01

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 25, 2001

Dear Dr. Hanks:

Enclosed is notification 01-024-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

By number	01-024-22n	Applicant #:	2001-250XRAB
Received:	January 24, 2001	Effective:	February 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: HI KS MN MO			
Release destination: MN			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature **(b) (6), (b) (7)(C)**

Date: 2-28-01

State: MN

Rptloc01/R4



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An Equal Opportunity Employer

MAR 1 2001

OR120018_BR_007872



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 25, 2001

Dear Mr. Brown:

Enclosed is notification 01-024-22n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-22n Applicant #: 2001-250XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MN MO
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

W State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/2/01

State: MD

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 5 2001

OR120018_BR_007873

February 28, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 28, 2001.

Interstate movement and Release
Notification no. 01-024-22n (2001-250XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

OR120018_BR_007874

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept of Agric., Jefferson City, MO
S. Wood, PPQ, NER, SER, Raleigh, NC
R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-024-22n

CONFIDENTIAL

**2001 Wheat Field Test Report
USDA #01-024-22n Monsanto #2001-250XRAB**

October 2, 2002

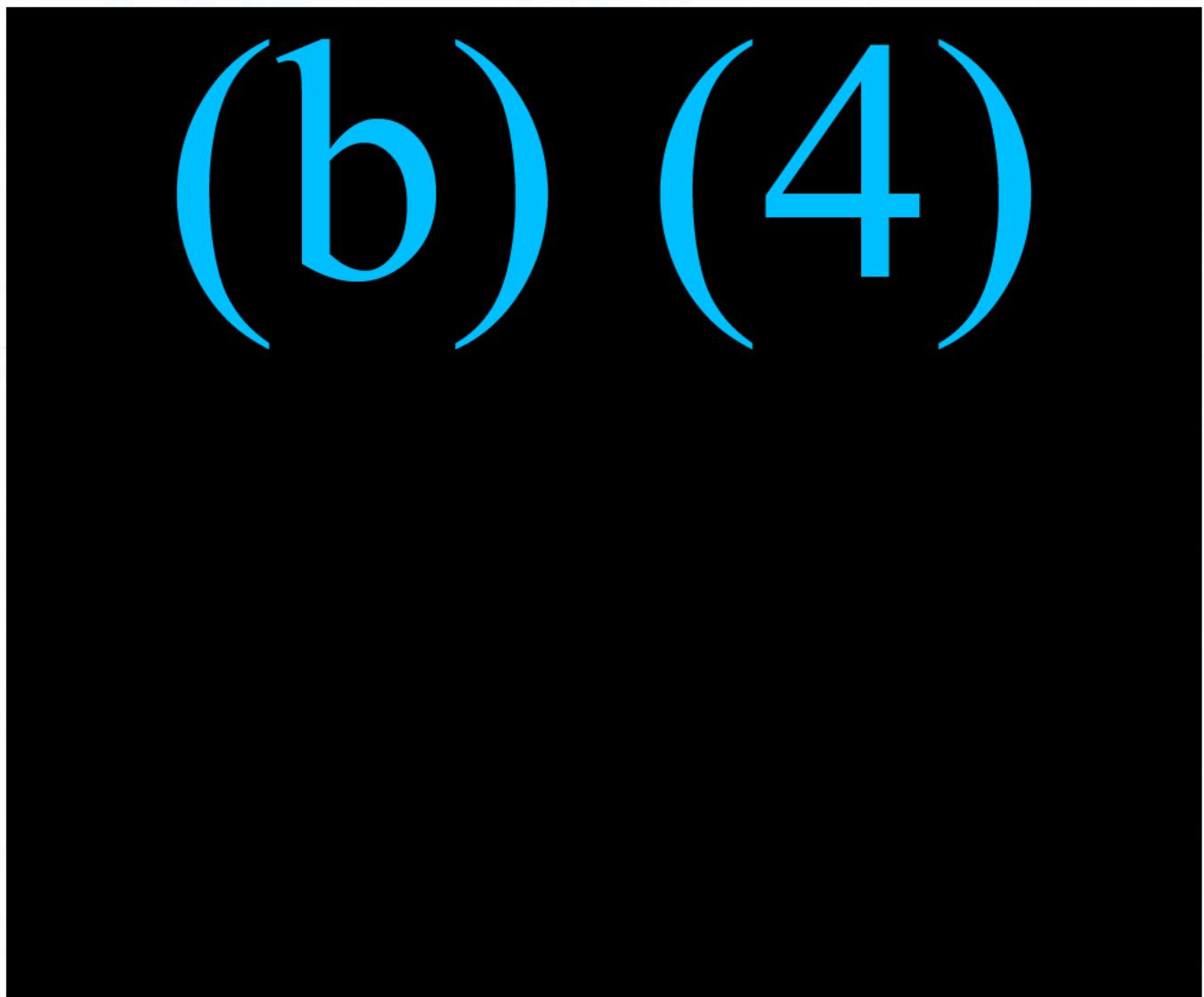
**Biotech Field Compliance Team
Monsanto Company**

Location
8025

County
Dakota County

State
MN

Dakota County/MN (8025)



(b) (4)

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-024-22n Monsanto #2001-250XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
8025	Dakota County	MN

Dakota County/MN (8025)

Planting Date: 05/15/2001

Harvest Date: 08/09/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981).

Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

=====
 Bp number: 01-024-23n
 =====

App number: 2001-252XRAB Begin movement: 2/21/01
 Received: 1/24/01 End movement: 2/21/02
 Institution: Monsanto Begin release: 2/21/01
 Recipient: Wheat End release: 2/21/02
 Status: Pending Acre: 12.00
 Effective date: 2/23/01 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant

Comments:

Resp person:

(b) (6), (b) (7)(C)

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax:

636-737-7085

=====

Initial

Date

1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[apd]	[1/25/01]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[RZR]*	[JAN 29 2001]
3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i>	[KLnD]	[1/30/01]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg			
Interstate	*Dest*HI	*	*WR	*	[]	[]
Interstate	*Dest*KS	*	*SCR	*	[]	[]
Interstate	*Dest*MO	*	*SCR	*	[]	[]
Interstate	*Dest*WA	*	*WR	*	[]	[]
Interstate	*Orig*HI	*	*WR	*		
Interstate	*Orig*KS	*	*SCR	*		
Interstate	*Orig*MO	*	*SCR	*		
Interstate	*Orig*WA	*	*WR	*		
Release	*	*WA	*	2*WR	*	

5. <input checked="" type="checkbox"/> Enter genes into database	[apd]	[1/29/01]
6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw	[KLnD]	[2/23/01]*
7. <input checked="" type="checkbox"/> Enter final data into database	[KLnD]	[2/28/01]
8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

*bioholder
H&H*

MONSANTO

Food • Health • Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63108
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-252XRAB

Permit Unit

January 22, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-024-23n

1. USDA Reference Number

2. Applicant Reference Number 2001-252XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release

February 21, 2001 - February 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety BW251

CONFIDENTIAL

Monsanto Reference ID

2001-252XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [REDACTED]

(b)(4)

CBI

[REDACTED]
(b)(4)

Gene: CTP2-CP4-- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3'-- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [REDACTED]

(b)(4)

CBI

[REDACTED]
(b)(4)

Gene: CTP2-CP4-- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3'-- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-252XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 50,000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, WA

DESTINATION:

HI, KS, MO, WA

Ship From:

HI

*[REDACTED] (b)(4) Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C), HI, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)
] - CBI

KS

*[REDACTED] (b)(4) Sedgwick County/Province, KS (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,
] - CBI

MO

*[REDACTED] (b)(4), St. Louis County/Province, MO, (b)(4)
U.S.A.
CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
U.S.A., (b) (4), (b) (6), (b) (7)(C)
] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-252XRAB

WA

*[(b) (4), (b) (6), (b) (7)(C) Grant County/Province, WA, (b) (4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4) USA

] - CBI

Ship To:

HI

*[County/Province, HI (b)(4) (b)(4) U.S.A. Honolulu
CONTACT: (b) (4), (b) (6), (b) (7)(C) HI (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

KS

*[(b)(4) Sedgwick County/Province, KS (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) KS, (b) (4) USA,

] - CBI

MO

*[U.S.A. (b)(4) St. Louis County/Province, MO (b)(4)

CONFIDENTIAL

Monsanto Reference ID

2001-252XRAB

CONTACT: [REDACTED]
U.S.A. [REDACTED] (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

[REDACTED] MO, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

*[REDACTED] (b) (4), (b) (6), (b) (7)(C) Grant County/Province, WA [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) WA, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-252XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (2)

WA

(b) (4), (b) (6), (b) (7)(C)

Grant County/Province, WA,

USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
WA, USA

] - CBI

(b) (4), (b) (6), (b) (7)(C) Grant County/Province, WA, USA, 7 acres.

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
WA, USA

] - CBI

MONSANTO

Food • Health • Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-252XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 22, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

CBI Justification
Notification 2001-252XRAB
Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

Monsanto Reference ID

2001-252XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-024-23n

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

January 22, 2001

1. USDA Reference Number

2. Applicant Reference Number 2001-252XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North
St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release

February 21, 2001 - February 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety BW251

CBI-DELETED

Monsanto Reference ID

2001-252XRAB

designation of transformed line: 33391**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-252XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 50,000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, WA

DESTINATION:

HI, KS, MO, WA

Ship From:**HI**[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.**KS**[CBI Deleted] -- *Sedgwick County/Province, KS, USA**MO**[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.**WA**[CBI Deleted] -- *Grant County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-252XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

WA

[CBI Deleted] -- *Grant County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-252XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (2)

WA

[CBI Deleted] -- Grant County/Province, WA, USA, 5 acres

[CBI Deleted] -- Grant County/Province, WA, USA, 7 acres

MONSANTO

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CBI-DELETED

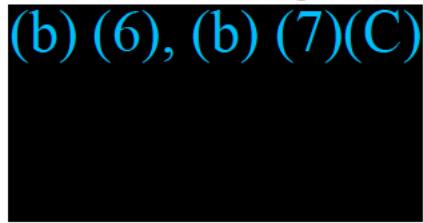
Monsanto Reference ID

2001-252XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 22, 2001

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

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Monsanto Reference ID

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

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January 22, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-024-23n

1. USDA Reference Number

2. Applicant Reference Number 2001-252XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 21, 2001 - February 21, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety BW251

CBI-DELETED

Monsanto Reference ID

2001-252XRAB

designation of transformed line: 33391**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

No marker

CBI-DELETED

Monsanto Reference ID

2001-252XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 50,000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, WA

DESTINATION:

HI, KS, MO, WA

Ship From:**HI**

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

WA

[CBI Deleted] -- *Grant County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-252XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

WA

[CBI Deleted] -- *Grant County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-252XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (2)

WA

[CBI Deleted] -- Grant County/Province, WA, USA, 5 acres

[CBI Deleted] -- Grant County/Province, WA, USA, 7 acres

MONSANTO

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CBI-DELETED

Monsanto Reference ID

2001-252XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 22, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 25, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-024-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-23n Applicant #: 2001-252XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO WA
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[Signature]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007905

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 25, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-024-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-23n Applicant #: 2001-252XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO WA
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|SJ|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007906

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 25, 2001

Dear Mr. Brown:

Enclosed is notification 01-024-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-23n Applicant #: 2001-252XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO WA
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

IS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007907

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 25, 2001

Dear Mr. Wessels:

Enclosed is notification 01-024-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-23n Applicant #: 2001-252XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO WA
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[Signature]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007908



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 25, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-024-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-024-23n	Applicant #:	2001-252XRAB
Received:	January 24, 2001	Effective:	February 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: HI KS MO WA			
Release destination: WA			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA



STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol I. Okada

Signature: (b) (6), (b) (7)(C)

Date: 22 February 2001

State: Hawaii

Rptloc01/R4



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FEB 23 2001

OR120018_BR_007909



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 25, 2001

Dear Mr. Brown:

Enclosed is notification 01-024-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-23n Applicant #: 2001-252XRAB
Received: January 24, 2001 Effective: February 23, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO WA
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael B. Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/2/01

State: MD

Rptloc01/R4

FEB 5 2001



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OR120018_BR_007910



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 25, 2001

Dear Mr. Wessels:

Enclosed is notification 01-024-23n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-024-23n	Applicant #:	2001-252XRAB
Received:	January 24, 2001	Effective:	February 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: HI KS MO WA			
Release destination: WA			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

[REDACTED]
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/1/01

State: WA

Rptloc01/R4



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FEB 2 2001

OR120018_BR_007911

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 23, 2001.

Interstate movement and Release
Notification no. 01-024-23n (2001-252XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

OR120018_BR_007912

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-024-23n

MODE = MEMORY TRANSMISSION

START=FEB-27 10:28

END=FEB-27 10:34

FILE NO.=522

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK	S	916367377085	004/004	00:05:38



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

***** - *****

***** - *****

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to
7 CFR 340.3(c), effective on or after February 23, 2001.

Interstate movement and Release
Notification no. 01-024-23n (2001-252XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

(b) (6), (b) (7)(C)

D-6

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure



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OR120018_BR_007914

CONFIDENTIAL

**2001 Wheat Field Test Report
USDA #01-024-23n Monsanto #2001-252XRAB**

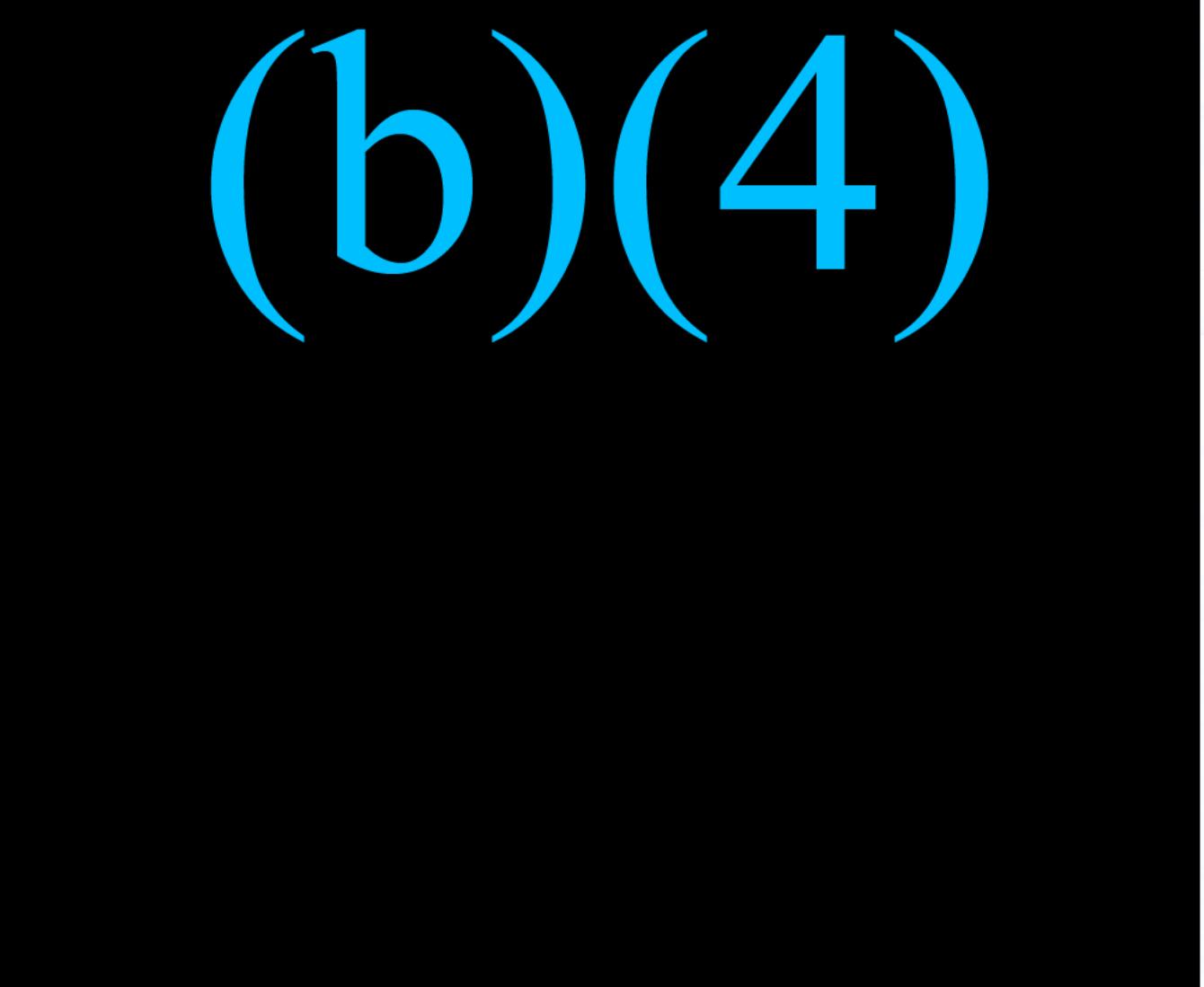
October 16, 2002

**Biotech Field Compliance Team
Monsanto Company**

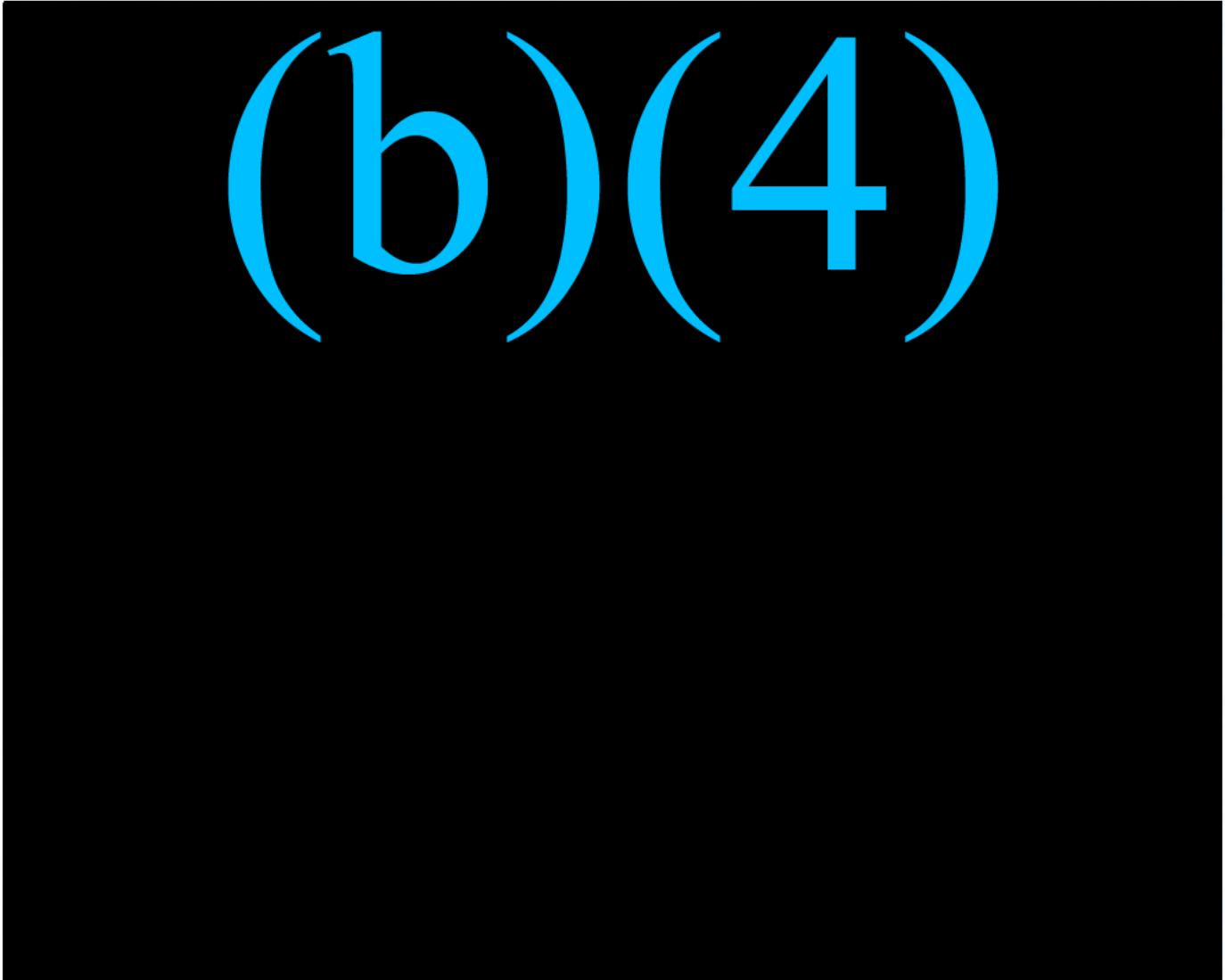
<u>Location</u>	<u>County</u>	<u>State</u>
2147307583	Grant County	WA
2147307598	Grant County	WA

Grant County/WA (2147307583)

(b)(4)



(b)(4)



CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-024-23n Monsanto #2001-252XRAB**

October 16, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147307583	Grant County	WA
2147307598	Grant County	WA

Grant County/WA (2147307583)

Planting Date: 04/23/2001

Harvest Date: 08/17/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Grant County/WA (2147307598)

Planting Date: 04/19/2001

Harvest Date: 08/17/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

=====
 Bp number: 01-024-25n
 =====

App number: 2001-280XRAB Begin movement: 2/22/01
 Received: 1/24/01 End movement: 2/22/02
 Institution: Monsanto Begin release: 2/22/01
 Recipient: Wheat End release: 2/22/02
 Status: Pending Acre: 6.00
 Effective date: 2/23/01 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant

Comments:

Resp person: [REDACTED]
 Parsed name: [REDACTED]

Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198

Telephone: [REDACTED] Fax: 636-737-7085

=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[apd]	[1/25/01]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[RIR]*	JAN 29 2001
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KLnD]	[1/30/01]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg				
Interstate	*Dest*MT	*	*WR	*	[]	[]	
Interstate	*Dest*WA	*	*WR	*	[]	[]	
Interstate	*Orig*MT	*	*WR	*	[]	[]	
Interstate	*Orig*WA	*	*WR	*	[]	[]	
Release	*	*WA	*	3*WR	*	[]	[]

5. <input checked="" type="checkbox"/> Enter genes into database	[apd]	[1/29/01]
6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw	[KLnD]	[2/8/01]*
7. <input checked="" type="checkbox"/> Enter final data into database	[KLnD]	[2/9/01]
8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

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CONFIDENTIAL

Monsanto Reference ID

2001-280XRAB

Permit Unit

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

January 23, 2001

01-024-25n

1. USDA Reference Number

2. Applicant Reference Number 2001-280XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Monsanto Company

FAX 636/737-7085

700 Chesterfield Parkway North
St. Louis MO

EMail (b) (6), (b) (7)(C)@monsanto.com

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2001 - February 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

CONFIDENTIAL

Monsanto Reference ID

2001-280XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- [REDACTED]

(b) (4) [REDACTED]
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- [REDACTED]

(b) (4) [REDACTED]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-280XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 2,000 Kg. wheat seed to and from each location.

ORIGIN: MT, WA
DESTINATION: MT, WA

Ship From:**MT**

* [REDACTED] (b) (4) Gallatin County/Province, MT (b) (4) USA
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MT, [REDACTED] (b) (4), USA,
] - CBI

WA

*[REDACTED] (b) (4) Whitman County/Province,
WA, (b) (4) USA
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED]
WA, (b) (4), (b) (6), (b) (7)(C) USA, [REDACTED] (b) (4), (b) (6), (b) (7)(C)
] - CBI

Ship To:**MT**

* [REDACTED] (b) (4) Gallatin County/Province, MT (b) (4) USA
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MT, [REDACTED] (b) (4), USA,
] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-280XRAB

WA

*[(b) (4)] USA Whitman County/Province,
WA, (b) (4) USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] USA, [(b) (4), (b) (6), (b) (7)(C)]

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-280XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (3)

WA

(b) (4)

Whitman County/Province, WA, USA,

2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C)

Adams County/Province, WA, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4)

Whitman County/Province, WA, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

Food • Health • Hope



CONFIDENTIAL

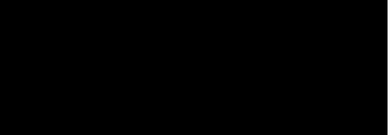
Monsanto Reference ID

2001-280XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 23, 2001

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

CBI Justification
Notification 2001-280XRAB
Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

**NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND
EXPRESSED TRAITS**

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

Monsanto Reference ID

2001-280XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-024-25n

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

January 23, 2001

1. USDA Reference Number

2. Applicant Reference Number 2001-280XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North
St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2001 - February 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

CBI-DELETED

Monsanto Reference ID

2001-280XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-280XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 2,000 Kg. wheat seed to and from each location.

ORIGIN:

MT, WA

DESTINATION:

MT, WA

Ship From:

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA**Ship To:**

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID
2001-280XRAB

CBI-DELETED

Monsanto Reference ID

2001-280XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (3)

WA

[CBI Deleted] -- Whitman County/Province, WA, USA, 2 acres

[CBI Deleted] -- Adams County/Province, WA, USA, 2 acres

[CBI Deleted] -- Whitman County/Province, WA, USA, 2 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID

2001-280XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)
[Redacted Content]

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63108

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

Monsanto Company

January 23, 2001

MONSANTO

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CBI-DELETED

Monsanto Reference ID

2001-280XRAB

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63108
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Permit Unit

January 23, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-024-25n

1. USDA Reference Number

2. Applicant Reference Number 2001-280XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2001 - February 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

CBI-DELETED

Monsanto Reference ID

2001-280XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

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CBI

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Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

New marker

CBI-DELETED

Monsanto Reference ID

2001-280XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 2,000 Kg. wheat seed to and from each location.

ORIGIN:

MT, WA

DESTINATION:

MT, WA

Ship From:

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA**Ship To:**

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-280XRAB

CBI-DELETED

Monsanto Reference ID

2001-280XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (3)

WA

[CBI Deleted] -- Whitman County/Province, WA, USA, 2 acres

[CBI Deleted] -- Adams County/Province, WA, USA, 2 acres

[CBI Deleted] -- Whitman County/Province, WA, USA, 2 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

Monsanto Reference ID

2001-280XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 23, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

file copy

Ms. Mary Bryson, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 25, 2001

Dear Ms. Bryson:

Enclosed is notification 01-024-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-024-25n	Applicant #:	2001-280XRAB
Received:	January 24, 2001	Effective:	February 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MT WA		
Release destination:	WA		

Should you have comments, please respond by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007944

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 25, 2001

Dear Mr. Wessels:

Enclosed is notification 01-024-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-024-25n	Applicant #:	2001-280XRAB
Received:	January 24, 2001	Effective:	February 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MT WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

ISI

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007945



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Ms. Mary Bryson, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 25, 2001

Dear Ms. Bryson:

Enclosed is notification 01-024-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-024-25n
Received: January 24, 2001
Institution: Monsanto
Interstate destination: MT WA
Release destination: WA

Applicant #: 2001-280XRAB
Effective: February 23, 2001
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5187 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2-2-01

State: Montana

Rpt1oc01/R4



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OR120018_BR_007946

FEB 2 2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

January 25, 2001

Dear Mr. Wessels:

Enclosed is notification 01-024-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-024-25n	Applicant #:	2001-280XRAB
Received:	January 24, 2001	Effective:	February 23, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: MT WA			
Release destination: WA			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/1/01

State: WA

Rptloc01/R4



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An Equal Opportunity Employer

FEB 2 2001

OR120018_BR_007947

February 8, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 23, 2001.

Interstate movement and Release
Notification no. 01-024-25n (2001-280XRAB)
Regulated article - Wheat
Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

CC:

M. Bryson, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
File number 01-024-25n

OR120018_BR_007948

Confirmation Report-Memory Send

Time : Feb-09-01 10:25am
Tel line 1 :
Tel line 2 :
Name :

Job number : 278
Date : Feb-09 10:24am
To : 916367377085
Document Pages : 01
Start time : Feb-09 10:24am
End time : Feb-09 10:25am
Pages sent : 01
Job number : 278

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

February 8, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 23, 2001.

Interstate movement and Release
Notification no. 01-024-23n (2001-280XRA8);
Regulated article - Wheat
Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

CC:
M. Bryson, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoake, PPO, WR, Sacramento, CA



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An Equal Opportunity Employer

OR120018_BR_007949

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-024-25n Monsanto #2001-280XRAB

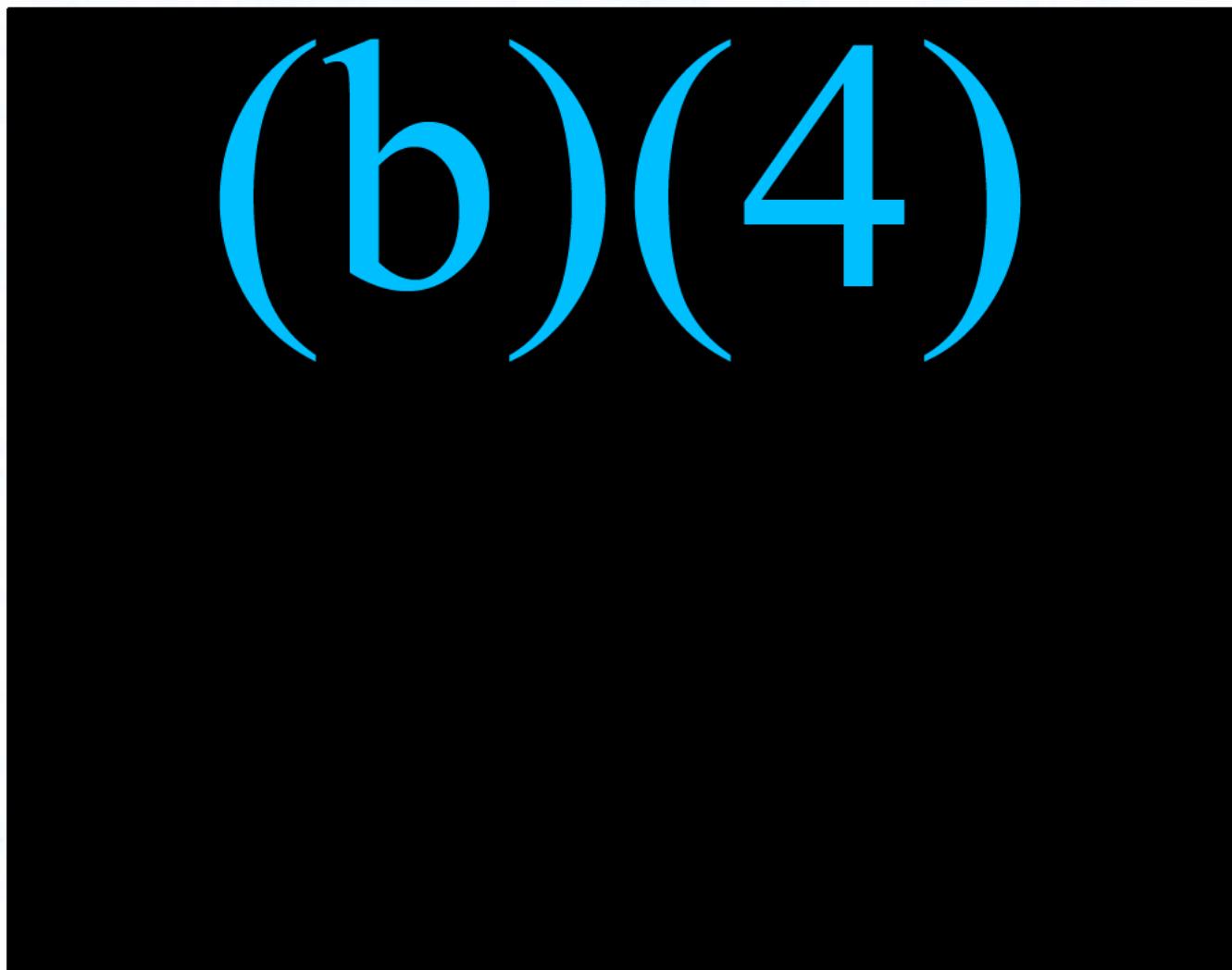
October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
2147307638	Whitman County	WA	Not Planted
2147306778	Adams County	WA	Not Planted
2147306763	Whitman County	WA	

Whitman County/WA (2147306763)

(b)(4)



(b)(4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-024-25n Monsanto #2001-280XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
2147307638	Whitman County	WA	Not Planted
2147306778	Adams County	WA	Not Planted
2147306763	Whitman County	WA	

Whitman County/WA (2147306763)

Planting Date: 05/08/2001

Harvest Date: 09/07/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

=====
 Bp number: 01-025-10n
 =====

App number: 2001-284XRAB Begin movement: 2/22/01
 Received: 1/25/01 End movement: 2/22/02
 Institution: Monsanto Begin release: 2/22/01
 Recipient: Wheat End release: 2/22/02
 Status: Pending Acre: 15.00
 Effective date: 2/24/01 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax:

636-737-7085

(b) (6), (b) (7)(C)

		Initial	Date
1.	[<input checked="" type="checkbox"/>] Assign Bp number and initial data entry	[apd]	[1/25/01]
2.	[<input type="checkbox"/>] Review by biotechnologist	[JT]*	[1/29/01]*
3.	[<input type="checkbox"/>] Letter of notification to State Fed-ex	[KLn]	[1/30/01]*
4.	[<input type="checkbox"/>] State response		

O/d	Loc	Site	Reg			
Interstate	*Dest*HI	*	*WR	*	[]	[]
Interstate	*Dest*KS	*	*SCR	*	[]	[]
Interstate	*Dest*MO	*	*SCR	*	[]	[]
Interstate	*Dest*MT	*	*WR	*	[]	[]
Interstate	*Orig*HI	*	*WR	*		
Interstate	*Orig*KS	*	*SCR	*		
Interstate	*Orig*MO	*	*SCR	*		
Interstate	*Orig*MT	*	*WR	*		
Release	*	*MT	*	1*WR	*	

5.	[<input checked="" type="checkbox"/>] Enter genes into database	[apd]	[1/29/01]
6.	[<input type="checkbox"/>] Letter of acknowledgement/denial/withdraw	[KLn]	[2/24/01]*
7.	[<input type="checkbox"/>] Enter final data into database	[KLn]	[2/28/01]
8.	[<input type="checkbox"/>] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

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CONFIDENTIAL

Monsanto Reference ID

2001-284XRAB

Permit Unit

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

January 23, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-025-10n

1. USDA Reference Number

2. Applicant Reference Number 2001-284XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2001 - February 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety WestBred 926, WestBred 936, Conan.

CONFIDENTIAL

Monsanto Reference ID

2001-284XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b)(4)
(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

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Monsanto Reference ID

2001-284XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 50,000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, MT

DESTINATION:

HI, KS, MO, MT

Ship From:**HI***[REDACTED] (b)(4) Honolulu
County/Province, HI, (b)(4) U.S.A.CONTACT: (b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)
] - CBI**KS***[REDACTED] (b)(4) Sedgwick County/Province, KS (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) Wichita, KS (b) (4) USA,
] - CBI**MO***[REDACTED] (b)(4) St. Louis County/Province, MO (b)(4)
U.S.A.
CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) St. Louis, MO (b) (4)
U.S.A., [REDACTED]
] - CBI**MT**

*[REDACTED] (b)(4) Gallatin County/Province, MT, (b)(4) USA

CONFIDENTIAL

Monsanto Reference ID

2001-284XRAB

CONTACT: [REDACTED]
[REDACTED] (b) (4), (b) (6), (b) (7)(C)
] - CBI

(b) (4), (b) (6), (b) (7)(C)

MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

Ship To:**HI**

*[REDACTED] (b)(4) Honolulu
County/Province, HI, [REDACTED] (b)(4) U.S.A.

CONTACT: [REDACTED]
[REDACTED] (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)
[REDACTED], HI, [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED]

] - CBI

KS

*[REDACTED] (b)(4) Sedgwick County/Province, KS (b)(4) USA
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] (b) (4), (b) (6), (b) (7)(C) KS, [REDACTED] USA,
[REDACTED]

] - CBI

MO

*[REDACTED] (b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.
CONTACT: [REDACTED]
U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] (b) (4), (b) (6), (b) (7)(C) MO, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-284XRAB

MT

*[(b)(4) Gallatin County/Province, MT (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) (b)(4), (b)(6), (b)(7)(C) MT, (b)(4) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-284XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

(b)(4)

Gallatin County/Province, MT, U.S.A, 15 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

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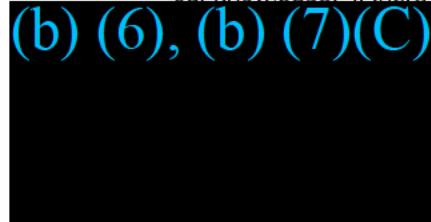
Monsanto Reference ID

2001-284XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 23, 2001

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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Monsanto Reference ID

2001-284XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-025-10n

1. USDA Reference Number

2. Applicant Reference Number 2001-284XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2001 - February 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety WestBred 926, WestBred 936, Conan.

MONSANTO COMPANY

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<http://www.monsanto.com>

January 23, 2001

CBI-DELETED

Monsanto Reference ID

2001-284XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-284XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 50,000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, MT

DESTINATION:

HI, KS, MO, MT

Ship From:**HI**[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.**KS**[CBI Deleted] -- *Sedgwick County/Province, KS, USA**MO**[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.**MT**[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-284XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID
2001-284XRAB

CBI-DELETED

Monsanto Reference ID

2001-284XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

[CBI Deleted] -- Gallatin County/Province, MT, U.S.A, 15 acres

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CBI-DELETED

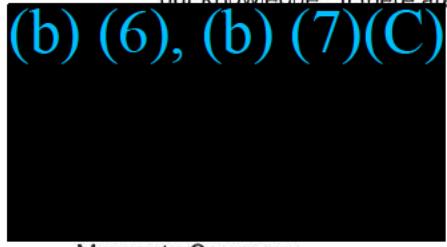
Monsanto Reference ID

2001-284XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 23, 2001

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700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

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<http://www.monsanto.com>

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Permit Unit

January 23, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

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1. USDA Reference Number

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Monsanto Company

700 Chesterfield Parkway North
St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2001 - February 22, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety WestBred 926, WestBred 936, Conan.

CBI-DELETED

Monsanto Reference ID

2001-284XRAB

designation of transformed line: 33391**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-284XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 50,000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MO, MT

DESTINATION:

HI, KS, MO, MT

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-284XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-284XRAB

CBI-DELETED

Monsanto Reference ID

2001-284XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

[CBI Deleted] -- Gallatin County/Province, MT, U.S.A, 15 acres

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CBI-DELETED

Monsanto Reference ID

2001-284XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

January 23, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
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<http://www.monsanto.com>

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 25, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-025-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-025-10n Applicant #: 2001-284XRAB
Received: January 25, 2001 Effective: February 24, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO MT
Release destination: MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[SJ]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007981

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 25, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-025-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-025-10n Applicant #: 2001-284XRAB
Received: January 25, 2001 Effective: February 24, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO MT
Release destination: MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|SJ|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007982

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 25, 2001

Dear Mr. Brown:

Enclosed is notification 01-025-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-025-10n Applicant #: 2001-284XRAB
Received: January 25, 2001 Effective: February 24, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO MT
Release destination: MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[SJ]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007983

file copy

Ms. Mary Bryson, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 25, 2001

Dear Ms. Bryson:

Enclosed is notification 01-025-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-025-10n Applicant #: 2001-284XRAB
Received: January 25, 2001 Effective: February 24, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO MT
Release destination: MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[Signature]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_007984

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

January 25, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-025-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-025-10n Applicant #: 2001-284XRAB
Received: January 25, 2001 Effective: February 24, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO MT
Release destination: MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

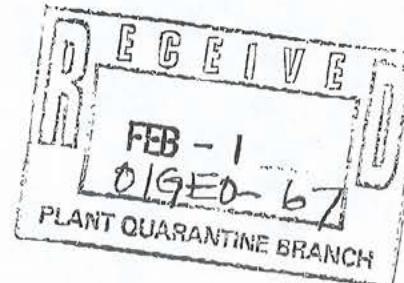
Sincerely,

[S]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA



STATE RESPONSE TO NOTIFICATION

X

State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol I. Okada

Signature: (b) (6), (b) (7)(C)

Date: 22 February 2001

State: Hawaii

Rptloc01/R4

FEB 23 2001

OR120018_BR_007985

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 25, 2001

Dear Mr. Brown:

Enclosed is notification 01-025-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-025-10n Applicant #: 2001-284XRAB
Received: January 25, 2001 Effective: February 24, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO MT
Release destination: MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[Signature]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Elliston, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 2/2/01

State: MO

Rptloc01/R4

FEB 5 2001

OR120018_BR_007986

Ms. Mary Bryson, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 25, 2001

Dear Ms. Bryson:

Enclosed is notification 01-025-10n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-025-10n Applicant #: 2001-284XRAB
Received: January 25, 2001 Effective: February 24, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MO MT
Release destination: MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[S]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2-2-01

State: Montana

Rptloc01/R4

FEB 2 2001

OR120018_BR_007987

February 24, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 24, 2001.

Interstate movement and Release
Notification no. 01-025-10n (2001-284XRAB)
Regulated article - Wheat
Destinations - Hawaii, Kansas, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept of Agric., Jefferson City, MO
L. Witham, Montana Dept. of Agric., Helena, MT
R. Stoaks, PPQ, WR, SCR, Sacramento, CA

File number 01-025-10n

OR120018_BR_007988

CONFIDENTIAL

**2001 Wheat Field Test Report
USDA #01-025-10n Monsanto #2001-284XRAB**

September 26, 2002

**Biotech Field Compliance Team
Monsanto Company**

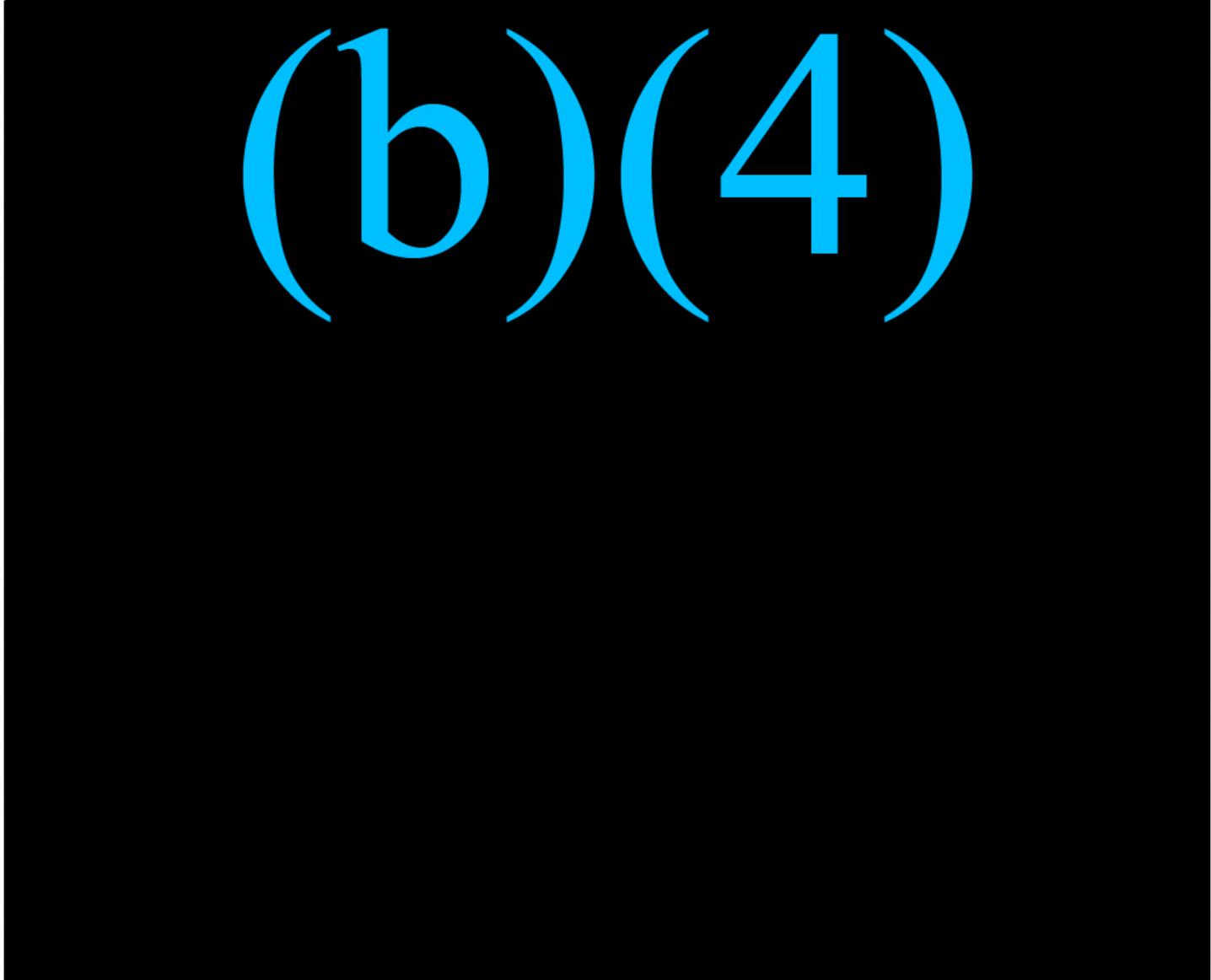
Location
340

County
Gallatin County

State
MT

Gallatin County/MT (340)

(b)(4)



(b)(4)

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-025-10n Monsanto #2001-284XRAB**

September 26, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
340	Gallatin County	MT

Gallatin County/MT (340)

Planting Date: 05/09/2001

Harvest Date: 09/21/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

=====
 Bp number: 01-037-11n
 =====

App number: 2001-338XRAB Begin movement: 3/07/01
 Received: 2/06/01 End movement: 3/07/02
 Institution: Monsanto Begin release: 3/07/01
 Recipient: Wheat End release: 3/07/02
 Status: Pending Acre: 25.00
 Effective date: 3/08/01 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: [REDACTED] (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[apd]	[2/12/01]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[RLR]*	FEB 12 2001
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KLD]	[2/15/01]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg	[]	[]	[]
Interstate	*Dest*HI	*	*WR *	[]	[]	[]
Interstate	*Dest*ID	*	*WR *	[]	[]	[]
Interstate	*Dest*KS	*	*SCR *	[]	[]	[]
Interstate	*Dest*MO	*	*SCR *	[]	[]	[]
Interstate	*Dest*WA	*	*WR *	[]	[]	[]
Interstate	*Orig*HI	*	*WR *			
Interstate	*Orig*ID	*	*WR *			
Interstate	*Orig*KS	*	*SCR *			
Interstate	*Orig*MO	*	*SCR *			
Interstate	*Orig*WA	*	*WR *			
Release	*	*ID *	4*WR *	[]	[]	[]
Release	*	*WA *	1*WR *	[]	[]	[]

5. <input checked="" type="checkbox"/> Enter genes into database	[apd]	[2/12/01]
6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw	[KLD]	[3/23/01]*
7. <input checked="" type="checkbox"/> Enter final data into database	[KLD]	[3/26/01]
8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

Reason for tardiness: (KS)&(MO) did not respond

MONSANTO

Food • Health • Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-338XRAB

Permit Unit

February 05, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-037-11n

1. USDA Reference Number

2. Applicant Reference Number 2001-338XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Monsanto Company

FAX 636/737-7085

700 Chesterfield Parkway North

EMail (b) (6), (b) (7)(C)@monsanto.com

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 07, 2001 - March 07, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2001-338XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [REDACTED]

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [REDACTED]

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-338XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

HI, ID, KS, MO, WA

DESTINATION:

HI, ID, KS, MO, WA

Ship From:

HI

*[(b)(4)] County/Province, HI, (b)(4) U.S.A. (b)(4) Honolulu
CONTACT: (b)(4), (b)(6), (b)(7)(C) (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)
] - CBI

ID

*[(b)(4)] Latah County/Province, ID (b)(4) USA
CONTACT: (b)(4), (b)(6), (b)(7)(C) (b)(4), (b)(6), (b)(7)(C) ID, (b)(4), (b)(6), (b)(7)(C) USA,
] - CBI

KS

*[(b)(4)] Sedgwick County/Province, KS (b)(4) USA
CONTACT: (b)(4), (b)(6), (b)(7)(C) (b)(4), (b)(6), (b)(7)(C) KS (b)(4), (b)(6), (b)(7)(C) USA,
] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-338XRAB

MO

*[(b)(4)] St. Louis County/Province, MO, (b)(4)
U.S.A

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] (b) (4), (b) (6), (b) (7)(C) MO,
U.S.A, [(b) (4), (b) (6), (b) (7)(C)]] - CBI

WA

*[(b) (4), (b) (6), (b) (7)(C)] Adams County/Province, WA, [(b) (4), (b) (6), (b) (7)(C)] USA
CONTACT: [(b) (4), (b) (6), (b) (7)(C)] (b) (4), (b) (6), (b) (7)(C) ID, [(b) (4), (b) (6), (b) (7)(C)] USA,
] - CBI

Ship To:

HI

*[(b)(4)] Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] (b) (4), (b) (6), (b) (7)(C)
[(b) (4), (b) (6), (b) (7)(C)], HI, [(b) (4), (b) (6), (b) (7)(C)] U.S.A. [(b) (4), (b) (6), (b) (7)(C)]

] - CBI

ID

*[(b)(4)] Latah County/Province, ID, (b)(4) USA

CONFIDENTIAL

Monsanto Reference ID

2001-338XRAB

CONTACT: [REDACTED]
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ID, [REDACTED] USA,

] - CBI

KS

[REDACTED]
(b)(4)

Sedgwick County/Province, KS [REDACTED] (b)(4) USA

CONTACT: [REDACTED]
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

KS, [REDACTED] USA,

] - CBI

MO

[REDACTED]
(b)(4)

St. Louis County/Province, MO, [REDACTED] (b)(4)

U.S.A

CONTACT: [REDACTED]
(b) (4), (b) (6), (b) (7)(C)

U.S.A, [REDACTED]

(b) (4), (b) (6), (b) (7)(C)

MO,

] - CBI

WA

[REDACTED]
(b) (4), (b) (6), (b) (7)(C)

, Adams County/Province, WA [REDACTED] USA

CONTACT: [REDACTED]
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ID, [REDACTED] USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-338XRAB

CONFIDENTIAL

Monsanto Reference ID

2001-338XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (4), WA (1)

ID

(b)(4) Latah County/Province, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)] - CBI

(b)(4) Moscow, Latah County/Province, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)] - CBI

(b)(4) Moscow, Latah County/Province, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)] - CBI

(b)(4) Moscow, Latah County/Province, ID, USA, 5 acres.

CONFIDENTIAL

Monsanto Reference ID

2001-338XRAB

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) ID: (b) (4), (b) (6), (b) (7)(C) USA

(b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

(b) (4), (b) (6), (b) (7)(C)

Adams County/Province, WA, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) ID: (b) (4), (b) (6), (b) (7)(C) USA

(b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-338XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 05, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

CBI Justification
Notification 2001-338XRAB
Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-338XRAB

Permit Unit

February 05, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-037-11n

1. USDA Reference Number

2. Applicant Reference Number 2001-338XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 07, 2001 - March 07, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-338XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-338XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 4000 pounds of wheat seed to and from each location.

ORIGIN:

HI, ID, KS, MO, WA

DESTINATION:

HI, ID, KS, MO, WA

Ship From:**HI**[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.**ID**[CBI Deleted] -- *Latah County/Province, ID, USA**KS**[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2001-338XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

WA

[CBI Deleted] -- *Adams County/Province, WA, USA

Ship To:**HI**

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

ID

[CBI Deleted] -- *Latah County/Province, ID, USA

CBI-DELETED

Monsanto Reference ID

2001-338XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

WA

[CBI Deleted] -- *Adams County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-338XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (4), WA (1)

ID

[CBI Deleted] -- Latah County/Province, ID, USA, 5 acres

[CBI Deleted] -- Latah County/Province, ID, USA, 5 acres

[CBI Deleted] -- Latah County/Province, ID, USA, 5 acres

[CBI Deleted] -- Latah County/Province, ID, USA, 5 acres

CBI-DELETED

Monsanto Reference ID
2001-338XRAB

WA

[CBI Deleted] -- Adams County/Province, WA, USA, 5 acres

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

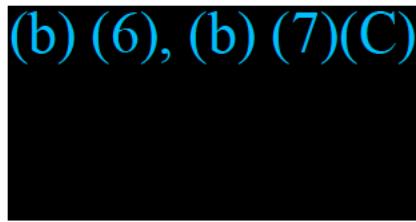
Monsanto Reference ID

2001-338XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 05, 2001

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2001-338XRAB

February 05, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-037-11n

1. USDA Reference Number

2. Applicant Reference Number 2001-338XRAB

3. Applicant/Responsible Party

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700 Chesterfield Parkway North
St. Louis MO

63198

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Interstate Movement and Release

March 07, 2001 - March 07, 2002

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Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

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CBI

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CBI-DELETED

Monsanto Reference ID

2001-338XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

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HI, ID, KS, MO, WA

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[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2001-338XRAB

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WA

[CBI Deleted] -- *Adams County/Province, WA, USA

Ship To:

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[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

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CBI-DELETED

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[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

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[CBI Deleted] -- *Adams County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-338XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (4), WA (1)

ID

[CBI Deleted] -- Latah County/Province, ID, USA, 5 acres

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[CBI Deleted] -- Latah County/Province, ID, USA, 5 acres

CBI-DELETED

Monsanto Reference ID

2001-338XRAB

WA

[CBI Deleted] -- Adams County/Province, WA, USA, 5 acres

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CBI-DELETED

MONSANTO COMPANY

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CHESTERFIELD, MISSOURI 63198
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Monsanto Reference ID

2001-338XRAB

9. Certification

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(b) (6), (b) (7)(C)



Monsanto Company

February 05, 2001

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

February 9, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-037-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-037-11n Applicant #: 2001-338XRAB
Received: February 6, 2001 Effective: March 8, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI ID KS MO WA
Release destination: ID WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008024

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 9, 2001

Dear Dr. Vega:

Enclosed is notification 01-037-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-037-11n Applicant #: 2001-338XRAB
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Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008025

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 9, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-037-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-037-11n Applicant #: 2001-338XRAB
Received: February 6, 2001 Effective: March 8, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI ID KS MO WA
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Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Wood, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008026

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 9, 2001

Dear Mr. Brown:

Enclosed is notification 01-037-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-037-11n Applicant #: 2001-338XRAB
Received: February 6, 2001 Effective: March 8, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI ID KS MO WA
Release destination: ID WA

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It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Wood, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008027

Confirmation Report-Memory Send

Time : Mar-22-01 06:05pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 031
Date : Mar-22 06:04pm
To : 915737510005
Document Pages : 09
Start time : Mar-22 06:04pm
End time : Mar-22 06:05pm
Pages sent : 09

Job number : 031 *** SEND SUCCESSFUL ***

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 9, 2001

Dear Mr. Brown:

Enclosed is notification 01-037-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

By number 01-037-11n Applicant #: 2001-338XRAB
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Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Wood, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008028



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

February 9, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-037-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-037-11n Applicant #: 2001-338KRAB
 Received: February 6, 2001 Effective: March 8, 2001
 Institution: Monsanto Recipient: Wheat
 Interstate destination: HI ID KS MO WA
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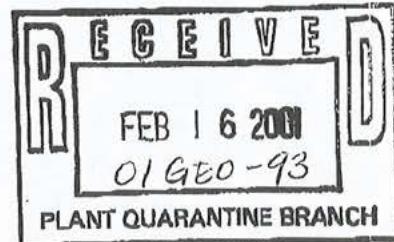
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Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine



Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813 (Oahu).
 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 26 February 2001

State: Hawaii

Rptloc01/R4



APHIS • Protecting American Agriculture

An Equal Opportunity Employer

FEB 27 2001

OR120018_BR_008029



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

RECEIVED

FEB 16 2001

PLANT INDUSTRIES

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 9, 2001

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Enclosed is notification 01-037-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-037-11n	Applicant #:	2001-338XRAB
Received:	February 6, 2001	Effective:	March 8, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: HI ID KS MO WA			
Release destination: ID WA			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature: (b) (6), (b) (7)(C)

Date: Feb. 22, 2001

State: IDAHO

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_008030

FEB 23 2001

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 9, 2001

Dear Mr. Brown:

Enclosed is notification 01-037-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 360.3 (c).

Bp Number 01-037-11n Applicant #: 2001-338XRAB
Received: February 6, 2001 Effective: March 8, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI ID KS MO WA
Release destination: ID WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 360.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Wood, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 3/27/01

State: MO

Rptloc01/R4

dup.

OR120018_BR_008031

3/23/2001

United States
Department of
AgricultureAnimal and
Plant Health
Inspection Service4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 9, 2001

Dear Mr. Brown:

Enclosed is notification 01-037-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (a).

Bp number 01-037-11n Applicant #: 2001-338XRAB
Received: February 6, 2001 Effective: March 8, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI ID KS MO WA
Release destination: ID WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Wood, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of state official: Michael E. Brown

Signature: _____

(b) (6), (b) (7)(C)

Date: 6/1/01

State: MO

Rpeloc01/R4

3/23/2001

dcp.

OR120018_BR_008032

TOTAL P.02



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 9, 2001

Dear Mr. Wessels:

Enclosed is notification 01-037-11n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-037-11n	Applicant #:	2001-338XRAB
Received:	February 6, 2001	Effective:	March 8, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: HI ID KS MO WA			
Release destination: ID WA			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/20/01

State: WA

Rptloc01/R4



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FEB 21 2001

OR120018_BR_008033

March 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 23, 2001.

Interstate movement

Notification no. 01-037-11n (2001-338XRAB)

Regulated article - Wheat

Destinations - Hawaii, Idaho, Kansas, Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813 (Oahu), upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
R. Vega, Idaho Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
S. Wood, PPQ, ER, Raleigh, NC

File number 01-037-11n

OR120018_BR_008034

Confirmation Report-Memory Send

Time : Mar-23-01 07:15pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 083
Date : Mar-23 07:14pm
To : 916367377085
Document Pages : 01
Start time : Mar-23 07:14pm
End time : Mar-23 07:15pm
Pages sent : 01

Job number : 083 *** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 23, 2001.

Interstate movement
Notification no. 01-037-11n (2001-338XRB)
Regulated article - Wheat
Destinations - Hawaii, Idaho, Kansas, Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Iialo Street, Honolulu, Hawaii 96813 (Oahu), upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
R. Vega, Idaho Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stroaks, PPQ, WR, Sacramento, CA
S. Wood, PPQ, ER, Raleigh, NC



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OR120018_BR_008035

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-037-11n Monsanto #2001-338XRAB

October 16, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147303312	Latah County	ID
2147303313	Latah County	ID
2147303313	Latah County	ID Not Planted
2147303313	Latah County	ID Not Planted
2147306778	Adams County	WA

Latah County/ID (2147303312)

(b)(4)

(b)(4)

Latah County/ID (2147303313)

(b)(4)

Adams County/WA (2147306778)

(b)(4)

(b)(4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. ILS, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-037-11n Monsanto #2001-338XRAB**

October 16, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147303312	Latah County	ID
2147303313	Latah County	ID
2147303313	Latah County	ID Not Planted
2147303313	Latah County	ID Not Planted
2147306778	Adams County	WA

Latah County/ID (2147303312)

Planting Date: 05/11/2001

Harvest Date: 09/11/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Latah County/ID (2147303313)

Planting Date: 04/23/2001

Destruct Date: 07/10/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Adams County/WA (2147306778)

Planting Date: 04/05/2001

Destruct Date: 06/27/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

2/09/01 12:33 pm

Notification Tracking Sheet

=====
 Bp number: 01-037-12n
 =====

App number: 2001-339XRAB Begin movement: 3/07/01
 Received: 2/06/01 End movement: 3/07/02
 Institution: Monsanto Begin release: 3/07/01
 Recipient: Wheat End release: 3/07/02
 Status: Pending Acre: 12.00
 Effective date: 3/08/01 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax:

636-737-7085

(b) (6), (b) (7)(C)

	Initial	Date
1. [✓] Assign Bp number and initial data entry	[apd]	[2/12/01]
2. [✓] Review by biotechnologist	[RZR]*	FEB 12 2001*
3. [✓] Letter of notification to State Fed-ex	[KLN]	[2/15/01]*
4. [] State response		

O/d	Loc	Site	Reg			
Interstate	*Dest*MT	*	*WR	*	[]	[]
Interstate	*Dest*WA	*	*WR	*	[]	[]
Interstate	*Orig*MT	*	*WR	*		
Interstate	*Orig*WA	*	*WR	*		
Release	*	*MT	*	5*WR	*	[]
Release	*	*WA	*	1*WR	*	[]
5. [✓]	Enter genes into database				[apd]	[2/12/01]
6. [✓]	Letter of acknowledgement/denial/withdraw				[KLN]	[2/23/01]*
7. [✓]	Enter final data into database				[KLN]	[2/26/01]
8. []	If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify					

MONSANTO

Food • Health • Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63108
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-339XRAB

Permit Unit

February 05, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-037-12n

1. USDA Reference Number

2. Applicant Reference Number 2001-339XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 07, 2001 - March 07, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

CONFIDENTIAL

Monsanto Reference ID

2001-339XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [REDACTED]

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [REDACTED]

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-339XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 2000 kg. wheat seed to and from each location.

ORIGIN:

MT, WA

DESTINATION:

MT, WA

Ship From:

MT

*[(b)(4)] Pondera County/Province, MT, (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b)(4), (b)(6), (b)(7)(C) USA,
[(b) (4), (b) (6), (b) (7)(C)] - CBI

[(b) (4), (b) (6), (b) (7)(C)] Pondera County/Province, MT, (b)(4), (b)(6), (b)(7)(C) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b)(4), (b)(6), (b)(7)(C) USA,
[(b) (4), (b) (6), (b) (7)(C)] - CBI

*[(b) (4), (b) (6), (b) (7)(C)] Pondera County/Province, MT, (b)(4), (b)(6), (b)(7)(C) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b)(4), (b)(6), (b)(7)(C) USA,
[(b) (4), (b) (6), (b) (7)(C)] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-339XRAB

*[Larry VanDyke , 4285 Dyk Road, Manhattan, Gallatin County/Province, MT, 59741, USA

CONTACT: Dale Clark, Western Plant Breeders, 8111 Timberline Drive, Bozeman, MT, 59718, USA,
406/587-1218
] - CBI

*[(b)(4) Gallatin County/Province, MT (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) (b)(4) (b) (4), (b) (6), (b) (7)(C) (b)(4) USA
USA, (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
] - CBI

*[(b)(4) Gallatin County/Province, MT, (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) (b)(4) (b) (4), (b) (6), (b) (7)(C) (b)(4) USA,
USA, (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
] - CBI

WA

*[(b)(4) Walla Walla County/Province, WA (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) (b)(4) (b) (4), (b) (6), (b) (7)(C) (b)(4) USA,
USA, (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
] - CBI

Ship To:

MT
*[(b)(4) Pondera County/Province, MT (b)(4) USA

CONFIDENTIAL

Monsanto Reference ID

2001-339XRAB

CONTACT: [REDACTED]
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

[REDACTED] (b) (4), (b) (6), (b) (7)
Bozeman, MT, [REDACTED] USA,

] - CBI

*[REDACTED] (b) (4), (b) (6), (b) (7)(C) Pondera County/Province, MT, [REDACTED] (b) (4), (b) (6), (b) (7)
USA

CONTACT: [REDACTED]
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

[REDACTED] (b) (4), (b) (6), (b) (7)
MT, [REDACTED] USA,

] - CBI

*[(b) (4), (b) (6), (b) (7)(C)] Pondera County/Province, MT, [REDACTED] (b) (4), (b) (6), (b) (7)
USA

CONTACT: [REDACTED]
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

[REDACTED] (b) (4), (b) (6), (b) (7)
MT, [REDACTED] USA,

] - CBI

*[REDACTED] (b) (4), (b) (6), (b) (7)(C) Gallatin County/Province, MT, [REDACTED] (b) (4), (b) (6), (b) (7)
USA

CONTACT: [REDACTED]
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

[REDACTED] (b) (4), (b) (6), (b) (7)
MT, [REDACTED] USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-339XRAB

*[(b)(4) Gallatin County/Province, MT, (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b)(4) (b)(4) Gallatin County/Province, MT (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

] - CBI

WA
* (b)(4) Walla Walla County/Province, WA (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-339XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (5), WA (1)

MT

(b)(4)

Pondera County/Province, MT, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) Pondera County/Province, MT, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) Pondera County/Province, MT, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) Gallatin County/Province, MT, USA, 2 acres.

CONFIDENTIAL

Monsanto Reference ID

2001-339XRAB

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b)(4)

Gallatin County/Province, MT, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

(b)(4)

Walla Walla County/Province, WA, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

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700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-339XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 05, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

**NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND
EXPRESSED TRAITS**

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-339XRAB

Permit Unit

February 05, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-037-12n

1. USDA Reference Number

2. Applicant Reference Number 2001-339XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North
St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 07, 2001 - March 07, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Backcross progenies of transgenic Bobwhite and elite lines.

CBI-DELETED

Monsanto Reference ID

2001-339XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-339XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 2000 kg. wheat seed to and from each location.

ORIGIN:

MT, WA

DESTINATION:

MT, WA

Ship From:

MT

[CBI Deleted] -- *Pondera County/Province, MT, USA

[CBI Deleted] -- *Pondera County/Province, MT, USA

[CBI Deleted] -- *Pondera County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID
2001-339XRAB

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

Ship To:

MT

[CBI Deleted] -- *Pondera County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID
2001-339XRAB

[CBI Deleted] -- *Pondera County/Province, MT, USA

[CBI Deleted] -- *Pondera County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-339XRAB

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-339XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (5), WA (1)

MT

[CBI Deleted] -- Pondera County/Province, MT, USA, 2 acres

[CBI Deleted] -- Pondera County/Province, MT, USA, 2 acres

[CBI Deleted] -- Pondera County/Province, MT, USA, 2 acres

[CBI Deleted] -- Gallatin County/Province, MT, USA, 2 acres

CBI-DELETED

Monsanto Reference ID

2001-339XRAB

[CBI Deleted] -- Gallatin County/Province, MT, USA, 2 acres

WA

[CBI Deleted] -- Walla Walla County/Province, WA, USA, 2 acres

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-339XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

A large black rectangular redaction box covering the area where a signature would typically be placed.

Monsanto Company

February 05, 2001

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700 CHESTERFIELD PKWY NORTH
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CBI-DELETED

Monsanto Reference ID

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Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-037-12n

February 05, 2001

1. USDA Reference Number

2. Applicant Reference Number 2001-339XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 07, 2001 - March 07, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

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Monsanto Reference ID

2001-339XRAB

designation of transformed line:

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CBI

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GENE OF INTEREST

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CBI

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Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-339XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 2000 kg. wheat seed to and from each location.

ORIGIN:

MT, WA

DESTINATION:

MT, WA

Ship From:

MT

[CBI Deleted] -- *Pondera County/Province, MT, USA

[CBI Deleted] -- *Pondera County/Province, MT, USA

[CBI Deleted] -- *Pondera County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-339XRAB

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

Ship To:

MT

[CBI Deleted] -- *Pondera County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-339XRAB

[CBI Deleted] -- *Pondera County/Province, MT, USA

[CBI Deleted] -- *Pondera County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2001-339XRAB

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

CBI DELETED

Monsanto Reference ID

2001-339XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (5), WA (1)

MT

[CBI Deleted] -- Pondera County/Province, MT, USA, 2 acres

[CBI Deleted] -- Pondera County/Province, MT, USA, 2 acres

[CBI Deleted] -- Pondera County/Province, MT, USA, 2 acres

[CBI Deleted] -- Gallatin County/Province, MT, USA, 2 acres

CBI-DELETED

Monsanto Reference ID

2001-339XRAB

[CBI Deleted] -- Gallatin County/Province, MT, USA, 2 acres

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[CBI Deleted] -- Walla Walla County/Province, WA, USA, 2 acres

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CBI-DELETED

Monsanto Reference ID

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9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 05, 2001

file copy

Ms. Mary Bryson, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 9, 2001

Dear Ms. Bryson:

Enclosed is notification 01-037-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-037-12n Applicant #: 2001-339XRAB
Received: February 6, 2001 Effective: March 8, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: MT WA
Release destination: MT WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008075

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 9, 2001

Dear Mr. Wessels:

Enclosed is notification 01-037-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-037-12n Applicant #: 2001-339XRAB
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Institution: Monsanto Recipient: Wheat
Interstate destination: MT WA
Release destination: MT WA

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Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008076



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Ms. Mary Bryson, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 9, 2001

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Bp number	01-037-12n	Applicant #:	2001-339XRAB
Received:	February 6, 2001	Effective:	March 8, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MT WA		
Release destination:	MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Kiri Whitmore*

Signature: (b) (6), (b) (7)(C)

Date: *2/21/01*

State: *Montana*

Rptloc01/R4



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FEB 21 2001

OR120018_BR_008077



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 9, 2001

Dear Mr. Wessels:

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Bp number	01-037-12n	Applicant #:	2001-339XKAB
Received:	February 6, 2001	Effective:	March 8, 2001
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Interstate destination:	MT WA		
Release destination:	MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

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Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/20/01

State: WA

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 21 2001

OR120018_BR_008078

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 8, 2001.

Interstate movement and Release
Notification no. 01-037-12n (2001-339XRAB)
Regulated article - Wheat
Destinations - Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

CC:

M. Bryson, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, SCR, WR, Sacramento, CA
File number 01-037-12n

OR120018_BR_008079

MODE = MEMORY TRANSMISSION

START=FEB-23 17:44 END=FEB-23 17:59

FILE NO.=497

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK	8	916367377005	039/039	00:08:28

***** - * * * * * - - * * * * * -



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

February 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 8, 2001.

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This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials and the Regional Program Managers (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Bryson, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, SCR, NR, Sacramento, CA



APHIS • Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008080

M O N S A N T O

Food • Health • Hope



March 9, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms Hatmaker;

In reviewing Monsanto's acknowledged wheat notification an error was discovered in a release County. The USDA number is 01-037-12n, Monsanto id 2001-339XRAB. The county for (b) (4) should be Fergus. The release site address is the same.

If you have any questions, please call me my telephone number is (b) (6), (b) (7)(C)
(b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

cc: M. Bryson, Montana Dept. of Agric., Helena, MT
T. Wessels, Washington Dept of Agric., Olympia, WA
R. Stoaks, PPQ, SCR, WR, Sacramento, CA

OR120018_BR_008081

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-037-12n Monsanto #2001-339XRAB

October 16, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147308220	Pondera County	MT
2147308218	Pondera County	MT
2147308219	Pondera County	MT
2147308221	Gallatin County	MT
7498	Gallatin County	MT
2147308222	Walla Walla County	WA

Pondera County/MT (2147308220)

(b)(4)

(b)(4)

Pondera County/MT (2147308218)

(b)(4)

Gallatin County/MT (2147308221)

(b)(4)

(b)(4)

Gallatin County/MT (7498)

(b)(4)

(b)(4)

Walla Walla County/WA (2147308222)

(b)(4)

(b)(4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. ILS, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981).

Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018 BR_008087

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-037-12n Monsanto #2001-339XRAB**

October 16, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
2147308220	Pondera County	MT	
2147308218	Pondera County	MT	
2147308219	Pondera County	MT	Not Planted
2147308221	Gallatin County	MT	
7498	Gallatin County	MT	
2147308222	Walla Walla County	WA	

Pondera County/MT (2147308220)

Planting Date: 04/25/2001

Harvest Date: 08/23/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Pondera County/MT (2147308218)

Planting Date: 04/28/2001

Harvest Date: 08/22/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Gallatin County/MT (2147308221)

Planting Date: 05/04/2001

Harvest Date: 09/20/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Gallatin County/MT (7498)

Planting Date: 04/25/2001

Harvest Date: 08/22/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Walla Walla County/WA (2147308222)

Planting Date: 04/17/2001

Destruct Date: 06/21/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

=====
 Bp number: 01-040-02n
 =====

App number: 2001-344XRAB Begin movement: 3/08/01
 Received: 2/09/01 End movement: 3/08/02
 Institution: Monsanto Begin release: 3/08/01
 Recipient: Wheat End release: 3/08/02
 Status: Pending Acre: 4.00
 Effective date: 3/11/01 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: [REDACTED] (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[ajd]	[2/15/01]
2. <input type="checkbox"/> Review by biotechnologist	[CRP]*	[2-16-01]*
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KLN]	[2/22/01]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg				
Interstate	*Dest*ID	*	*WR	*	[]	[]	
Interstate	*Dest*MN	*	*NER	*	[]	[]	
Interstate	*Dest*MO	*	*SCR	*	[]	[]	
Interstate	*Dest*ND	*	*SCR	*	[]	[]	
Interstate	*Dest*SD	*	*SCR	*	[]	[]	
Interstate	*Orig*ID	*	*WR	*	[]	[]	
Interstate	*Orig*MN	*	*NER	*	[]	[]	
Interstate	*Orig*MO	*	*SCR	*	[]	[]	
Interstate	*Orig*ND	*	*SCR	*	[]	[]	
Interstate	*Orig*SD	*	*SCR	*	[]	[]	
Release	*	*ID	*	1*WR	*	[]	[]
Release	*	*MN	*	1*NER	*	[]	[]
Release	*	*ND	*	1*SCR	*	[]	[]
Release	*	*SD	*	1*SCR	*	[]	[]

5. Enter genes into database [ajd] [2/21/01]
 6. Letter of acknowledgement/denial/withdraw [KLN] [4/23/01]*
 7. Enter final data into database [KLN] [4/25/01]
 8. If deny, reason: Address incomplete, Signature mismatch,
 Ph category, Phenotype, Gene, Donor, Marker,
 Does not qualify

Reason for tardiness: (MN) responded on 4/23/2001.

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID

2001-344XRAB

Permit Unit

February 06, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-040-02n

1. USDA Reference Number

2. Applicant Reference Number 2001-344XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 08, 2001 - March 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite, a hard red, spring wheat

CONFIDENTIAL

Monsanto Reference ID

2001-344XRAB

designation of transformed line:

25397

Constructs: PV-TXGT05

GENE OF INTEREST

Promoter: CMP3/I5 -- [REDACTED]

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMoVa/I5 -- [REDACTED]

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

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Monsanto Reference ID

2001-344XRAB

7. Mode of Transformation

Particle Bombardment

8. Introduction

Interstate Movement and Release

Ship up to 200 pounds of wheat seeds and plant tissue samples (forage, hay, straw, grain)

ORIGIN:

ID, MN, MO, ND, SD

DESTINATION:

ID, MN, MO, ND, SD

Ship From:**ID**

*[REDACTED] (b)(4) Payette County/Province, ID (b)(4) U.S.A.
CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED], ID, (b) (6), (b) (7)(C), (b) (4)
U.S.A. [REDACTED]
] - CBI

MN

*[REDACTED] (b)(4) Wilkin County/Province,
MN, (b)(4) [REDACTED]
CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED]
MIN, (b) (6), (b) (7)(C), (b) (4) [REDACTED]
Comments: (b) (6), (b) (7)(C), (b) (4) [REDACTED]
] - CBI

MO

*[REDACTED] (b)(4) St. Louis County/Province, MO (b)(4) U.S.A.
CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED] MO, (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) [REDACTED]
] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-344XRAB

ND

*[(b)(4)] McHenry County/Province, ND, (b)(4) USA
CONTACT: (b) (6), (b) (7)(C), (b) (4) [(b)(6), (b)(7)(C), (b) (4)] ND, [(b)(6), (b)(7)(C), (b) (4)] USA
] - CBI

SD

*[SD, (b)(4)] (b)(4) Marshall County/Province,
CONTACT: SD (b) (6), (b) (7)(C), (b) (4) [(b)(6), (b)(7)(C), (b) (4)]
] - CBI

Ship To:

ID

*[(b)(4)] Payette County/Province, ID (b)(4) U.S.A.
CONTACT: (b) (6), (b) (7)(C), (b) (4) [(b)(6), (b)(7)(C), (b) (4)], ID, [(b)(6), (b)(7)(C), (b) (4)]
U.S.A., [(b)(6), (b)(7)(C), (b) (4)]
] - CBI

MN

*[MN, (b)(4)] (b)(4) Wilkin County/Province,

CONFIDENTIAL

Monsanto Reference ID

2001-344XRAB

CONTACT: (b) (6), (b) (7)(C), (b) (4)
[REDACTED] MN, (b) (6), (b) (7)(C), (b) (4)

] - CBI

MO

*[(b)(4) St. Louis County/Province, MO (b)(4) U.S.A.
CONTACT: (b) (6), (b) (7)(C), (b) (4) MO, [REDACTED] U.S.A.,
[REDACTED] (b) (6), (b) (7)(C), (b) (4)

] - CBI

ND

*[(b)(4) McHenry County/Province, ND (b)(4) USA
CONTACT: (b) (6), (b) (7)(C), (b) (4) ND, [REDACTED] USA

] - CBI

SD

*[(b)(4) Marshall County/Province,
SD, (b)(4)
CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED]
[REDACTED] SD, (b) (6), (b) (7)(C), (b) (4)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-344XRAB

CONFIDENTIAL

Monsanto Reference ID

2001-344XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

ID (1), MN (1), ND (1), SD (1)

ID

(b) (4)

Payette County/Province, ID, U.S.A., 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) ID, (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

] - CBI

MN

(b)(4)

Campbell, Wilkin County/Province,

MN, 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Comments: (b) (6), (b) (7)(C), (b) (4)] - CBI

ND

(b) (6), (b) (7)(C), (b) (4)

McHenry County/Province, ND, USA, 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)
ND (b) (6), (b) (7)(C), (b) (4) USA

(b) (6), (b) (7)(C), (b) (4)

] - CBI

SD

(b)(4)

Marshall County/Province, SD, USA, 1

acres.

CONFIDENTIAL

Monsanto Reference ID

2001-344XRAB

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) SD, (b) (6), (b) (7)(C), (b) (4)

] - CBI

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

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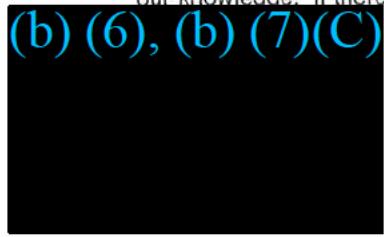
Monsanto Reference ID

2001-344XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 06, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63108
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-344XRAB

Permit Unit

February 06, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-040-02n

1. USDA Reference Number

2. Applicant Reference Number 2001-344XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 08, 2001 - March 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite, a hard red, spring wheat

CBI-DELETED

Monsanto Reference ID

2001-344XRAB

designation of transformed line:

25397

Constructs: PV-TXGT05**GENE OF INTEREST**

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMoVa/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-344XRAB

7. Mode of Transformation Particle Bombardment**8. Introduction** Interstate Movement and Release

Ship up to 200 pounds of wheat seeds and plant tissue samples (forage, hay, straw, grain)

ORIGIN:

ID, MN, MO, ND, SD

DESTINATION:

ID, MN, MO, ND, SD

Ship From:**ID**[CBI Deleted] -- *Payette County/Province, ID, U.S.A.**MN**[CBI Deleted] -- *Wilkin County/Province, MN**MO**[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-344XRAB

ND[CBI Deleted] -- *McHenry County/Province, ND, USA**SD**[CBI Deleted] -- *Marshall County/Province, SD**Ship To:****ID**[CBI Deleted] -- *Payette County/Province, ID, U.S.A.**MN**[CBI Deleted] -- *Wilkin County/Province, MN

CBI-DELETED

Monsanto Reference ID

2001-344XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

SD

[CBI Deleted] -- *Marshall County/Province, SD

CBI-DELETED

Monsanto Reference ID

2001-344XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

ID (1), MN (1), ND (1), SD (1)

ID[CBI Deleted] -- Payette County/Province, ID, U.S.A., 1 acres**MN**[CBI Deleted] -- Wilkin County/Province, MN, 1 acres**ND**[CBI Deleted] -- McHenry County/Province, ND, USA, 1 acres**SD**[CBI Deleted] -- Marshall County/Province, SD, USA, 1 acres

MONSANTO

Food • Health • Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-344XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 06, 2001

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700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
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CBI-DELETED

Monsanto Reference ID

2001-344XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 06, 2001

01-040-02n

1. USDA Reference Number

2. Applicant Reference Number 2001-344XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 08, 2001 - March 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite, a hard red, spring wheat

CBI-DELETED

Monsanto Reference ID

2001-344XRAB

designation of transformed line:

25397

Constructs: PV-TXGT05

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMoVa/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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mne

CBI-DELETED

Monsanto Reference ID

2001-344XRAB

7. Mode of Transformation Particle Bombardment**8. Introduction** Interstate Movement and Release

Ship up to 200 pounds of wheat seeds and plant tissue samples (forage, hay, straw, grain)

ORIGIN:

ID, MN, MO, ND, SD

DESTINATION:

ID, MN, MO, ND, SD

Ship From:**ID**[CBI Deleted] -- *Payette County/Province, ID, U.S.A.**MN**[CBI Deleted] -- *Wilkin County/Province, MN**MO**[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-344XRAB

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

SD

[CBI Deleted] -- *Marshall County/Province, SD

Ship To:

ID

[CBI Deleted] -- *Payette County/Province, ID, U.S.A.

MN

[CBI Deleted] -- *Wilkin County/Province, MN

CBI-DELETED

Monsanto Reference ID

2001-344XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

SD

[CBI Deleted] -- *Marshall County/Province, SD

CBI-DELETED

Monsanto Reference ID

2001-344XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

ID (1), MN (1), ND (1), SD (1)

ID[CBI Deleted] -- Payette County/Province, ID, U.S.A., 1 acres**MN**[CBI Deleted] -- Wilkin County/Province, MN, 1 acres**ND**[CBI Deleted] -- McHenry County/Province, ND, USA, 1 acres**SD**[CBI Deleted] -- Marshall County/Province, SD, USA, 1 acres

MONSANTO

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MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-344XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 06, 2001

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 15, 2001

Dear Dr. Vega:

Enclosed is notification 01-040-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-02n Applicant #: 2001-344XRAB
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008120

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 15, 2001

Dear Dr. Hanks:

Enclosed is notification 01-040-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-02n Applicant #: 2001-344XRAB
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008121

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 15, 2001

Dear Mr. Brown:

Enclosed is notification 01-040-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-02n Applicant #: 2001-344XRAB
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008122

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 15, 2001

Dear Mr. Nelson:

Enclosed is notification 01-040-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-02n Applicant #: 2001-344XRAB
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008123

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 15, 2001

Dear Mr. Fridley:

Enclosed is notification 01-040-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-02n Applicant #: 2001-344XRAB
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

ISI

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008124



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

RECEIVED

FEB 23 2001

PLANT INDUSTRIES

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 15, 2001

Dear Dr. Vega:

Enclosed is notification 01-040-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-02n Applicant #: 2001-344XRAB
 Received: February 9, 2001 Effective: March 11, 2001
 Institution: Monsanto Recipient: Wheat
 Interstate destination: ID MN MO ND SD
 Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
 Biotechnology Program Operations
 Permits and Risk Assessments
 Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature: (b) (6), (b) (7)(C)

Date: 2/23/01

State: IDAHO

Rptloc01/R4



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An Equal Opportunity Employer

FEB 23 2001

OR120018_BR_008125



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 15, 2001

Dear Dr. Hanks:

Enclosed is notification 01-040-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-02n Applicant #: 2001-344XRAB
 Received: February 9, 2001 Effective: March 11, 2001
 Institution: Monsanto Recipient: Wheat
 Interstate destination: ID MN MO ND SD
 Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. *with the attached conditions*

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 4-24-01

State: MN

Rptloc01/R4



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An Equal Opportunity Employer

OR120018_BR_008126

APR 23 2001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 15, 2001

Dear Mr. Brown:

Enclosed is notification 01-040-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-02n Applicant #: 2001-344XRAB
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Michael E Brown

Signature

(b) (6), (b) (7)(C)

Date:

3/7/01

State:

MO

Rptloc01/R4

MAR 12 2001



APHIS - Protecting American Agriculture

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OR120018_BR_008127



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 15, 2001 - ✓

Dear Mr. Nelson:

Enclosed is notification 01-040-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-02n Applicant #: 2001-344XRAB
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature: (b) (6), (b) (7)(C)

Date: 4-17-01

State: ND

Rptloc01/R4

See attached
letter
Conditions



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008128



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 15, 2001

Dear Mr. Fridley:

Enclosed is notification 01-040-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-02n Applicant #: 2001-344XRAB
 Received: February 9, 2001 Effective: March 11, 2001
 Institution: Monsanto Recipient: Wheat
 Interstate destination: ID MN MO ND SD
 Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
 Biotechnology Program Operations
 Permits and Risk Assessments
 Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA



STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: _____

State: _____

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

MAR 5 2001

OR120018_BR_008129

April 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 23, 2001.

Interstate movement and Release

Notification no. 01-040-02n (2001-344XRAB)

Regulated article - Wheat

Destinations - Idaho, Minnesota, Missouri, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota has (attached) supplemental conditions.

In addition, the State of North Dakota has (attached) supplemental conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

R. Vega, Idaho Dept. of Agric., Boise, ID
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 01-040-02n



Minnesota Department of Agriculture (651) 296-1277

April 24, 2001

Ms. Mary Jackson
Biotechnology Program Operations
Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

Fax: 301-734-8910

RE: Additional Conditions for Release of Wheat 01-040-02n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.
State Biotechnologist

AGRICULTURE COMMISSIONER
ROGER JOHNSON



PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE

State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: James White
USDA-APHIS-PPQ
Biotechnology Risk Assessment
4700 River Road
Riverdale MD 20737

E. Diane Hatmaker
USDA-APHIS-PPQ
Permits-Biotechnology
4700 River Road
Riverdale MD 20737

FROM: David R. Nelson [REDACTED] (b) (6), (b) (7)(C)

DATE: April 17, 2001

RE: Performance Standards for Wheat Notifications

We believe the performance standards for biotechnology wheat trials under notification or permit need to be strengthened to prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial. Standards should be stronger than those used for seed certification purposes because the needs of seed certification differ from the need to prevent persistence in the environment.

Biotechnology wheat trials planned for this and future growing seasons should incorporate the following safeguards:

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed. This distance reflects the pollen movement distances recognized by seed certification standards.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

CC

(b) (6), (b) (7)(C)

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-040-02n Monsanto #2001-344XRB

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
300278859	Payette County	ID
7958	Wilkin County	MN
2147308258	McHenry County	ND
1133	Marshall County	SD

Payette County/ID (300278859)

(b)(4)

(b)(4)

Wilkin County/MN (7958)

(b)(4)

McHenry County/ND (2147308258)

(b)(4)

Marshall County/SD (1133)

(b)(4)

(b)(4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure. OR120018_BR_008137

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-040-02n Monsanto #2001-344XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
300278859	Payette County	ID
7958	Wilkin County	MN
2147308258	McHenry County	ND
1133	Marshall County	SD

Payette County/ID (300278859)

Planting Date: 05/01/2001

Harvest Date: 08/13/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Wilkin County/MN (7958)

Planting Date: 05/12/2001

Harvest Date: 08/13/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

McHenry County/ND (2147308258)

Planting Date: 05/14/2001

Harvest Date: 08/15/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Marshall County/SD (1133)

Planting Date: 05/11/2001

Harvest Date: 08/10/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Bp number: 01-040-03n

App number:	2001-345XRAB	Begin movement:	3/08/01
Received:	2/09/01	End movement:	3/08/02
Institution:	Monsanto	Begin release:	3/08/01
Recipient:	Wheat	End release:	3/08/02
Status:	Pending	Acre:	4.00
Effective date:	3/11/01	CBI status:	CBI
Phenotype:	HT - Glyphosate tolerant		
Comments:			
Resp person:	(b) (6), (b) (7)(C)		
Parsed name:			
Address1:	Monsanto Company		
Address2:	700 Chesterfield Parkway N.		
Address3:			
Address4:			
City/State/Zip:	Chesterfield, MO 63198		
Telephone:	(b) (6), (b) (7)(C)	Fax:	636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[apd]	[2/15/01]
2. <input type="checkbox"/> Review by biotechnologist	[CRP]*	[2-16-01]*
3. <input checked="" type="checkbox"/> Letter of notification to State	[KLnD]	[2/22/01]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg			
Interstate	*Dest*ID	*	*WR *	[]	[]	[]
Interstate	*Dest*MN	*	*NER *	[]	[]	[]
Interstate	*Dest*MO	*	*SCR *	[]	[]	[]
Interstate	*Dest*ND	*	*SCR *	[]	[]	[]
Interstate	*Dest*SD	*	*SCR *	[]	[]	[]
Interstate	*Orig*ID	*	*WR *			
Interstate	*Orig*MN	*	*NER *			
Interstate	*Orig*MO	*	*SCR *			
Interstate	*Orig*ND	*	*SCR *			
Interstate	*Orig*SD	*	*SCR *			
Release	*	*ID	*	1*WR *	[]	[]
Release	*	*MN	*	1*NER *	[]	[]
Release	*	*ND	*	1*SCR *	[]	[]
Release	*	*SD	*	1*SCR *	[]	[]

5. <input checked="" type="checkbox"/> Enter genes into database	[apd]	[2/21/01]
6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw	[KLnD]	[4/23/01]*
7. <input checked="" type="checkbox"/> Enter final data into database	[KLnD]	[4/25/01]
8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

Reason for tardiness: (MN) responded on 4/23/2001.

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-345XRAB

Permit Unit

February 06, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-040-03n

1. USDA Reference Number

2. Applicant Reference Number 2001-345XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 08, 2001 - March 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite, a hard red, spring wheat

CONFIDENTIAL

Monsanto Reference ID

2001-345XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [REDACTED]

(b)(4)

CBI

[REDACTED]
(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [REDACTED]

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-345XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 200 pounds wheat seed and plant tissue samples (forage, hay, straw, grain)

ORIGIN:

ID, MN, MO, ND, SD

DESTINATION:

ID, MN, MO, ND, SD

Ship From:**ID**

*[REDACTED] (b)(4) Payette County/Province, ID, (b)(4) U.S.A.
CONTACT: (b) (4), (b) (6), (b) (7)(C) [REDACTED] ID, (b)(4)
U.S.A., [REDACTED]
] - CBI

MN

*[REDACTED] (b)(4) Wilkin County/Province,
MN, (b)(4) [REDACTED]
CONTACT: (b) (4), (b) (6), (b) (7)(C) [REDACTED]
MIN, (b) (4), (b) (6), (b) (7)(C) [REDACTED]
Comments: (b) (4), (b) (6), (b) (7)(C) [REDACTED]] - CBI

MO

*[REDACTED] (b)(4) St. Louis County/Province, MO, (b)(4), U.S.A.
CONTACT: (b) (4), (b) (6), (b) (7)(C) [REDACTED] MO, (b)(4), U.S.A.,
(b) (4), (b) (6), (b) (7)(C) [REDACTED]
] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-345XRAB

ND

* [REDACTED] (b)(4) McHenry County/Province, ND, [REDACTED] (b)(4) USA
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] Velva, ND, [REDACTED] (b)(4) USA
] - CBI

SD

*[REDACTED] SD, (b)(4) [REDACTED] (b)(4) Marshall County/Province,
CONTACT: [REDACTED] SD [REDACTED] (b) (4), (b) (6), (b) (7)(C)
] - CBI

Ship To:

ID

* [REDACTED] (b)(4) Payette County/Province, ID (b)(4) U.S.A.
CONTACT [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] e, ID [REDACTED]
U.S.A., (b)(4), (b)(6), (b)(7)(C)
] - CBI

MN

*[REDACTED] MN (b)(4) [REDACTED] (b)(4) Wilkin County/Province,
[REDACTED]

CONFIDENTIAL

Monsanto Reference ID

2001-345XRAB

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[REDACTED] (b)(4) St. Louis County/Province, MO, (b)(4) U.S.A.
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED], MO, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A.,
[REDACTED]

] - CBI

ND

*[REDACTED] (b)(4) McHenry County/Province, ND (b)(4) USA
CONTACT [REDACTED] (b) (4), (b) (6), (b) (7)(C) ND [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

SD

*[REDACTED] (b)(4) Britton, Marshall County/Province,
SD, (b)(4)
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED]
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2001-345XRAB

CONFIDENTIAL

Monsanto Reference ID

2001-345XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

ID (1), MN (1), ND (1), SD (1)

ID

(b)(4)

Payette County/Province, ID, U.S.A., 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

]- CBI

MN

(b)(4)

Wilkin County/Province,

MN, 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

]- CBI

ND

(b)(4)

McHenry County/Province, ND, USA, 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
ND, (b) (4), (b) (6), (b) (7)(C) USA

]- CBI

SD

(b)(4)

Marshall County/Province, SD, USA, 1

acres.

CONFIDENTIAL

Monsanto Reference ID

2001-345XRAB

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-345XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 06, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" if("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (IOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (IOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-345XRAB

Permit Unit

February 06, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-040-03n

1. USDA Reference Number

2. Applicant Reference Number 2001-345XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North
St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 08, 2001 - March 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite, a hard red, spring wheat

CBI-DELETED

Monsanto Reference ID

2001-345XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-345XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 200 pounds wheat seed and plant tissue samples (forage, hay, straw, grain)

ORIGIN:

ID, MN, MO, ND, SD

DESTINATION:

ID, MN, MO, ND, SD

Ship From:**ID**[CBI Deleted] -- *Payette County/Province, ID, U.S.A.**MN**[CBI Deleted] -- *Wilkin County/Province, MN**MO**[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-345XRAB

ND[CBI Deleted] -- *McHenry County/Province, ND, USA**SD**[CBI Deleted] -- *Marshall County/Province, SD**Ship To:****ID**[CBI Deleted] -- *Payette County/Province, ID, U.S.A.**MN**[CBI Deleted] -- *Wilkin County/Province, MN

CBI-DELETED

Monsanto Reference ID

2001-345XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

SD

[CBI Deleted] -- *Marshall County/Province, SD

CBI-DELETED

Monsanto Reference ID

2001-345XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

ID (1), MN (1), ND (1), SD (1)

ID[CBI Deleted] -- Payette County/Province, ID, U.S.A., 1 acres**MN**[CBI Deleted] -- Wilkin County/Province, MN, 1 acres**ND**[CBI Deleted] -- McHenry County/Province, ND, USA, 1 acres**SD**[CBI Deleted] -- Marshall County/Province, SD, USA, 1 acres

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-345XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 06, 2001

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700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

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CBI-DELETED

Monsanto Reference ID

2001-345XRAB

Permit Unit

February 06, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-040-03n

1. USDA Reference Number

2. Applicant Reference Number 2001-345XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 08, 2001 - March 08, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite, a hard red, spring wheat

CBI-DELETED

Monsanto Reference ID

2001-345XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

None

CBI-DELETED

Monsanto Reference ID

2001-345XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 200 pounds wheat seed and plant tissue samples (forage, hay, straw, grain)

ORIGIN:

ID, MN, MO, ND, SD

DESTINATION:

ID, MN, MO, ND, SD

Ship From:**ID**

[CBI Deleted] -- *Payette County/Province, ID, U.S.A.

MN

[CBI Deleted] -- *Wilkin County/Province, MN

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2001-345XRAB

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

SD

[CBI Deleted] -- *Marshall County/Province, SD

Ship To:

ID

[CBI Deleted] -- *Payette County/Province, ID, U.S.A.

MN

[CBI Deleted] -- *Wilkin County/Province, MN

CBI-DELETED

Monsanto Reference ID

2001-345XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

SD

[CBI Deleted] -- *Marshall County/Province, SD

CBI-DELETED

Monsanto Reference ID

2001-345XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (1), MN (1), ND (1), SD (1)

ID

[CBI Deleted] -- Payette County/Province, ID, U.S.A., 1 acres

MN

[CBI Deleted] -- Wilkin County/Province, MN, 1 acres

ND

[CBI Deleted] -- McHenry County/Province, ND, USA, 1 acres

SD

[CBI Deleted] -- Marshall County/Province, SD, USA, 1 acres

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MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

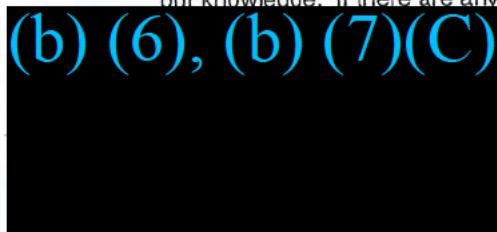
Monsanto Reference ID

2001-345XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 06, 2001

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 15, 2001

Dear Dr. Vega:

Enclosed is notification 01-040-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-03n Applicant #: 2001-345XRAB
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008170

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 15, 2001

Dear Dr. Hanks:

Enclosed is notification 01-040-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-03n Applicant #: 2001-345XRAB
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[SJ]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008171

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 15, 2001

Dear Mr. Brown:

Enclosed is notification 01-040-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-03n Applicant #: 2001-345XRAB
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008172

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 15, 2001

Dear Mr. Nelson:

Enclosed is notification 01-040-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-03n Applicant #: 2001-345XRAB
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008173

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 15, 2001

Dear Mr. Fridley:

Enclosed is notification 01-040-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-03n Applicant #: 2001-345XRAB
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

JS

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008174



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

RECEIVED

FEB 13 2001

PLANT INDUSTRIES

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

February 15, 2001

Dear Dr. Vega:

Enclosed is notification 01-040-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-040-03n	Applicant #:	2001-345XRAB
Received:	February 9, 2001	Effective:	March 11, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: ID MN MO ND SD			
Release destination: ID MN ND SD			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature: (b) (6), (b) (7)(C)

Date: 2/23/01

State: IDAHO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 23 2001

OR120018_BR_008175



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 15, 2001

Dear Dr. Hanks:

Enclosed is notification 01-040-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-03n Applicant #: 2001-345XRAB
 Received: February 9, 2001 Effective: March 11, 2001
 Institution: Monsanto Recipient: Wheat
 Interstate destination: ID MN MO ND SD
 Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination with the attached conditions

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 4-24-01

State: MN

Rptloc01/R4



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APR 23 2001

OR120018_BR_008176



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 15, 2001

Dear Mr. Brown:

Enclosed is notification 01-040-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-03n Applicant #: 2001-345XRAB
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 3/1/01

State: MD

Rptloc01/R4

MAR 12 2001



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OR120018_BR_008177



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 15, 2001

Dear Mr. Nelson:

Enclosed is notification 01-040-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-03n Applicant #: 2001-345XRAE
Received: February 9, 2001 Effective: March 11, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: ID MN MO ND SD
Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R. Nelson

Signature: (b) (6), (b) (7)(C)

Date: 4-17-01

State: ND

Rptloc01/R4

*See attached
letter
conditions*



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APR 18 2001

OR120018_BR_008178



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 15, 2001

Dear Mr. Fridley:

Enclosed is notification 01-040-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-040-03n Applicant #: 2001-345XRAB
 Received: February 9, 2001 Effective: March 11, 2001
 Institution: Monsanto Recipient: Wheat
 Interstate destination: ID MN MO ND SD
 Release destination: ID MN ND SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
 Biotechnology Program Operations
 Permits and Risk Assessments
 Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA



STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State Official: *Karen T. Bell*

Signature: (b) (6), (b) (7)(C)

Date: 3/1/01

State: South Dakota

Rptlcc01/R4



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MAR 5 2001

OR120018_BR_008179

April 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 23, 2001.

Interstate movement and Release

Notification no. 01-040-03n (2001-345XRAB)

Regulated article - Wheat

Destinations - Idaho, Minnesota, Missouri, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota has (attached) supplemental conditions.

In addition, the State of North Dakota has (attached) supplemental conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

[S]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

R. Vega, Idaho Dept. of Agric., Boise, ID
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 01-040-03n

**AGRICULTURE COMMISSIONER
ROGER JOHNSON**



PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: James White
USDA-APHIS-PPQ
Biotechnology Risk Assessment
4700 River Road
Riverdale MD 20737

E. Diane Hatmaker
USDA-APHIS-PPQ
Permits-Biotechnology
4700 River Road
Riverdale MD 20737

FROM: David R. Nelson

(b) (6), (b) (7)(C)

DATE: April 17, 2001

RE: Performance Standards for Wheat Notifications

We believe the performance standards for biotechnology wheat trials under notification or permit need to be strengthened to prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial. Standards should be stronger than those used for seed certification purposes because the needs of seed certification differ from the need to prevent persistence in the environment.

Biotechnology wheat trials planned for this and future growing seasons should incorporate the following safeguards:

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed. This distance reflects the pollen movement distances recognized by seed certification standards.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

CC

(b) (6), (b) (7)(C)



Minnesota Department of Agriculture (651) 296-1277

April 24, 2001

Ms. Mary Jackson
Biotechnology Program Operations
Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 20703

Fax: 301-734-8910

RE: Additional Conditions for Release of Wheat 01-040-03n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Franks, Ph.D.
State Biotechnologist

Confirmation Report-Memory Send

Time : Apr-24-01 05:07pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 755
Date : Apr-24 05:05pm
To : 916367377085
Document Pages : 03
Start time : Apr-24 05:05pm
End time : Apr-24 05:07pm
Pages sent : 03

Job number : 755

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

April 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 23, 2001.

Interstate movement and Release
Notification no. 01-040-02n (2001-344KRAB)
Regulated article - wheat
Destinations - Idaho, Minnesota, Missouri, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota has (attached) supplemental conditions.

In addition, the State of North Dakota has (attached) supplemental conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

R. Vega, Idaho Dept. of Agric., Boise, ID
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD



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OR120018_BR_008183

Confirmation Report-Memory Send

Time : Apr-24-01 05:05pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 754
Date : Apr-24 05:03pm
To : 916367377085
Document Pages : 03
Start time : Apr-24 05:04pm
End time : Apr-24 05:05pm
Pages sent : 03

Job number : 754

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

April 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to
7 CFR 340.3(c), effective on or after April 23, 2001.

Interstate movement and Release
Notification no. 01-040-03n (2001-345XRAB)
Regulated article - Wheat
Destinations - Idaho, Minnesota, Missouri, North Dakota, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package. This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota has (attached) supplemental conditions.

In addition, the State of North Dakota has (attached) supplemental conditions.
A copy of this letter of acknowledgment will be sent to the receiving state regulatory officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

CC:
R. Vega, Idaho Dept. of Agric., Boise, ID
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD



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OR120018_BR_008184

CONFIDENTIAL

**2001 Wheat Field Test Report
USDA #01-040-03n Monsanto #2001-345XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
300278859	Payette County	ID
7958	Wilkin County	MN
2147308258	McHenry County	ND
1133	Marshall County	SD

Payette County/ID (300278859)

(b)(4)

(b)(4)

Wilkin County/MN (7958)

(b)(4)

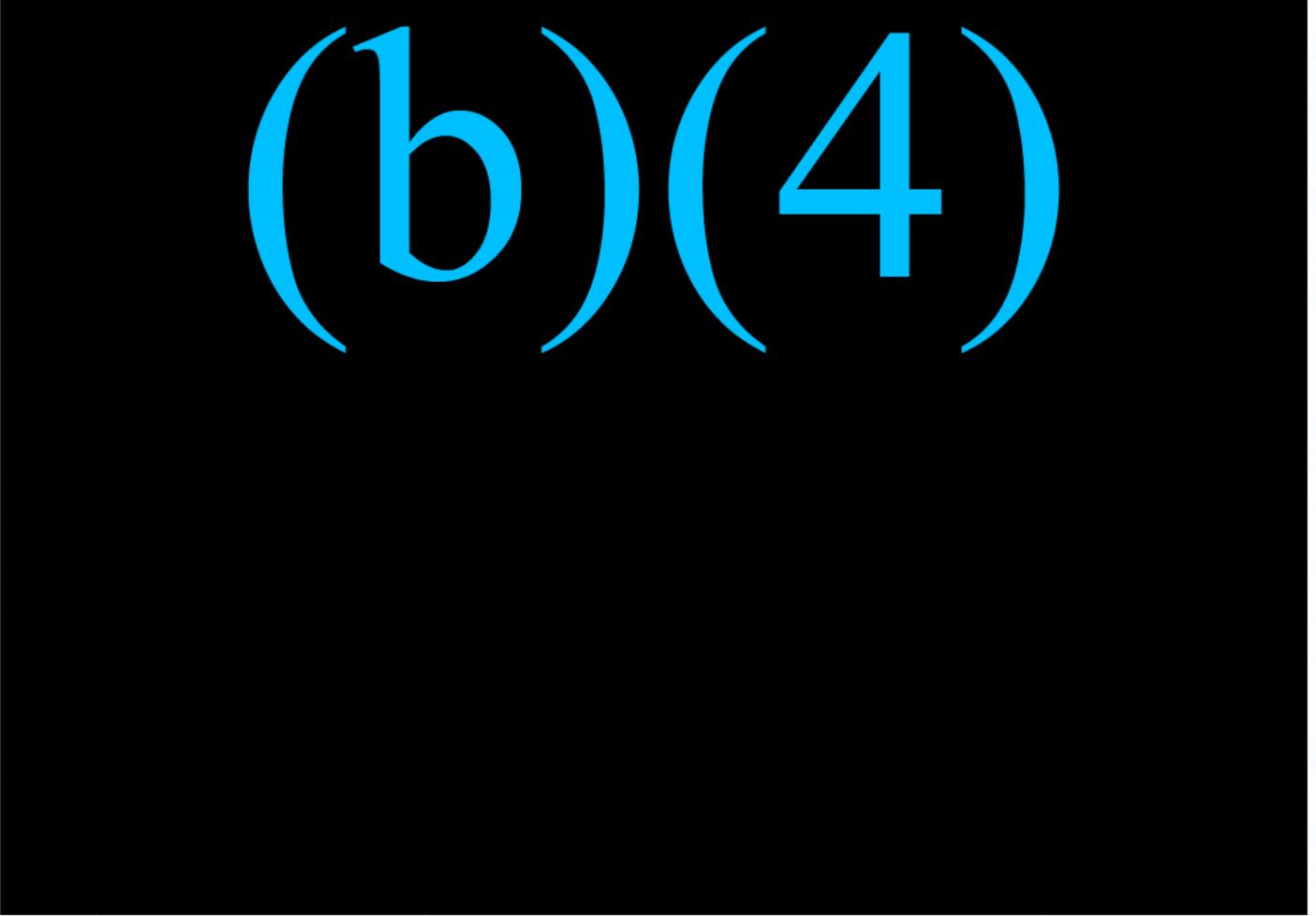
McHenry County/ND (2147308258)

(b)(4)

Marshall County/SD (1133)

(b)(4)

(b)(4)



CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppen, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (IOth Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-040-03n Monsanto #2001-345XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
300278859	Payette County	ID
7958	Wilkin County	MN
2147308258	McHenry County	ND
1133	Marshall County	SD

Payette County/ID (300278859)

Planting Date: 05/01/2001

Harvest Date: 08/13/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Wilkin County/MN (7958)

Planting Date: 05/12/2001

Harvest Date: 08/13/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

McHenry County/ND (2147308258)

Planting Date: 05/14/2001

Harvest Date: 08/15/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Marshall County/SD (1133)

Planting Date: 05/11/2001

Harvest Date: 08/10/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

=====
Bp number: 01-046-18n
=====

App number:	2001-356XRAB	Begin movement:	3/11/01
Received:	2/15/01	End movement:	3/11/02
Institution:	Monsanto	Begin release:	3/11/01
Recipient:	Wheat	End release:	3/11/02
Status:	Pending	Acre:	8.00
Effective date:	3/17/01	CBI status:	CBI
Phenotype:	HT - Glyphosate tolerant		
Comments:			
Resp person:	(b) (6), (b) (7)(C)		
Parsed name:			
Address1:	Monsanto Company		
Address2:	700 Chesterfield Parkway N.		
Address3:			
Address4:			
City/State/Zip:	Chesterfield, MO 63198		
Telephone:	(b) (6), (b) (7)(C)	Fax:	636-737-7085

=====

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[apd]	[2/22/01]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[AMK]*	[2/23/01]*
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KLN]	[2/27/01]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg			
Interstate	*Dest*HI	*	*WR *	[]	[]	[]
Interstate	*Dest*IA	*	*SCR *	[]	[]	[]
Interstate	*Dest*KS	*	*SCR *	[]	[]	[]
Interstate	*Dest*MO	*	*SCR *	[]	[]	[]
Interstate	*Dest*MT	*	*WR *	[]	[]	[]
Interstate	*Dest*ND	*	*SCR *	[]	[]	[]
Interstate	*Dest*SD	*	*SCR *	[]	[]	[]
Interstate	*Dest*WA	*	*WR *	[]	[]	[]
Interstate	*Orig*HI	*	*WR *			
Interstate	*Orig*IA	*	*SCR *			
Interstate	*Orig*KS	*	*SCR *			
Interstate	*Orig*MO	*	*SCR *			
Interstate	*Orig*MT	*	*WR *			
Interstate	*Orig*ND	*	*SCR *			
Interstate	*Orig*SD	*	*SCR *			
Interstate	*Orig*WA	*	*WR *			
Release	*	*MT	1*WR *	[]	[]	[]
Release	*	*ND	1*SCR *	[]	[]	[]
Release	*	*SD	1*SCR *	[]	[]	[]
Release	*	*WA	1*WR *	[]	[]	[]

Reason for tardiness : (ND) responded on 4/18/2001.

2/22/01 8:59 am

Notification Tracking Sheet

=====
Bp number: 01-046-18n
=====

App number: 2001-356XRAB Begin movement: 3/11/01
Received: 2/15/01 End movement: 3/11/02
Institution: Monsanto Begin release: 3/11/01
Recipient: Wheat End release: 3/11/02
Status: Pending Acre: 8.00
Effective date: 3/17/01 CBI status: CBI
Phenotype: HT - Glyphosate tolerant

Comments:

Resp person:
Parsed name:

Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.

Address3:
Address4:

City/State/Zip: Chesterfield MO 63198

Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

===== Initial Date

1. [] Assign Bp number and initial data entry [] []
2. [] Review by biotechnologist []* []*
3. [] Letter of notification to State [] []*
4. [] State response

	O/d Loc Site Reg		
5.	[<input checked="" type="checkbox"/>] Enter genes into database	[apd]	[2/23/01]
6.	[<input checked="" type="checkbox"/>] Letter of acknowledgement/denial/withdraw	[KLO]	[4/19/01]*
7.	[<input checked="" type="checkbox"/>] Enter final data into database	[KLO]	[4/20/01]
8.	If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

MONSANTO

Food • Health • Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-356XRAB

Permit Unit

February 09, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-046-18n

1. USDA Reference Number

2. Applicant Reference Number 2001-356XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 11, 2001 - March 11, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2001-356XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [REDACTED]

(b)(4)

CBI

[REDACTED]
(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [REDACTED]

(b)(4)

CBI

[REDACTED]
(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-356XRAB

designation of transformed line:

TA_S2520

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [REDACTED]

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 3' -- [REDACTED]

(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2001-356XRAB

designation of transformed line:

TA_S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [REDACTED]

(b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-356XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [REDACTED]

(b)(4) [REDACTED]

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-356XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 4,000 Kg. wheat seed to and from each location.

ORIGIN:

HI, IA, KS, MO, MT, ND, SD, WA

DESTINATION:

HI, IA, KS, MO, MT, ND, SD, WA

Ship From:**HI***[redacted] (b)(4) Honolulu
County/Province, HI, (b)(4) U.S.A.CONTACT: (b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)
]- CBI**IA***[redacted] (b)(4) Story County/Province, IA, (b)(4) U.S.A.
CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) IA, (b) (4), (b) (6), (b) (7)(C) U.S.A.,
]- CBI**KS***[redacted] (b)(4) Sedgwick County/Province, KS (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,
]- CBI

CONFIDENTIAL

Monsanto Reference ID

2001-356XRAB

MO

*[(b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.] - CBI
CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4),
U.S.A. (b) (4), (b) (6), (b) (7)(C) USA,
] - CBI

MT

*[(b)(4) Gallatin County/Province, MT, (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,
] - CBI

ND

*[(b) (4), (b) (6), (b) (7)(C) McHenry County/Province, ND
CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA,
] - CBI

SD

*[(b)(4) USA (b)(4) Brookings County/Province, SD,
CONTACT: (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA
] - CBI

WA

*[(b)(4) Whitman County/Province, WA, (b)(4) USA

CONFIDENTIAL

Monsanto Reference ID

2001-356XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4) USA

] - CBI

Ship To:**HI**

*[(b) (4)] County/Province, HI, (b) (4) U.S.A. Honolulu

CONTACT: (b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

IA

*[(b) (4)] Story County/Province, IA, (b) (4) U.S.A

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) IA, (b) (4) U.S.A,

] - CBI

KS

*[(b) (4)] Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-356XRAB

MO

*[(b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b)(4)
U.S.A.

] - CBI

MT

*[(b)(4) Gallatin County/Province, MT, (b)(4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) MT (b)(4) USA,
(b)(4), (b)(6), (b)(7)(C)

] - CBI

ND

*[(b) (4), (b) (6), (b) (7)(C) McHenry County/Province, ND
CONTACT: (b) (4), (b) (6), (b) (7)(C) ND (b)(4) USA,
(b)(4), (b)(6), (b)(7)(C)

] - CBI

SD

*[(b)(4) Brookings County/Province, SD,
(b)(4) USA

CONFIDENTIAL

Monsanto Reference ID

2001-356XRAB

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
[REDACTED] SD, [REDACTED] USA, [REDACTED]

] - CBI

WA

* [REDACTED] (b)(4) Whitman County/Province, WA, (b)(4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, [REDACTED] USA

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-356XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1), ND (1), SD (1), WA (1)

MT

(b) (4), (b) (6), (b) (7)(C)

Gallatin County/Province, MT, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) MT (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

ND

(b) (4), (b) (6), (b) (7)(C)

McHenry County/Province, ND, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

SD

(b)(4)

Brookings County/Province, SD,

USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

(b)(4)

Whitman County/Province, WA, USA, 2 acres.

CONFIDENTIAL

Monsanto Reference ID

2001-356XRAB

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

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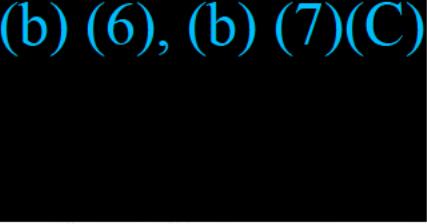
Monsanto Reference ID

2001-356XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 09, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

CBI Justification
Notification 2001-356XRAB
Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

**NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND
EXPRESSED TRAITS**

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

Monsanto Reference ID

2001-356XRAB

Permit Unit

February 09, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-046-18n

1. USDA Reference Number

2. Applicant Reference Number 2001-356XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North
St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 11, 2001 - March 11, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-356XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-356XRAB

designation of transformed line:

TA_S2520

Constructs: PV-TXGT13**GENE OF INTEREST**

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

CBI

Terminator: M1 3' -- [CBI Deleted]

CBI-DELETED

Monsanto Reference ID

2001-356XRAB

designation of transformed line:

TA_S9240

Constructs: PV-TXGT17**GENE OF INTEREST**

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-356XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215

Constructs: PV-TXGT23**GENE OF INTEREST**

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-356XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 4,000 Kg. wheat seed to and from each location.

ORIGIN:

HI, IA, KS, MO, MT, ND, SD, WA

DESTINATION:

HI, IA, KS, MO, MT, ND, SD, WA

Ship From:**HI**

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

IA

[CBI Deleted] -- *Story County/Province, IA, U.S.A

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2001-356XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

ND

[CBI Deleted] -- *McHenry County/Province, ND

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID
2001-356XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

IA

[CBI Deleted] -- *Story County/Province, IA, U.S.A

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2001-356XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

ND

[CBI Deleted] -- *McHenry County/Province, ND

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

CBI-DELETED

Monsanto Reference ID
2001-356XRAB

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-356XRAB

Release Site:**NUMBER OF STATES/TERRITORIES AND SITES:**

MT (1), ND (1), SD (1), WA (1)

MT[CBI Deleted] -- Gallatin County/Province, MT, USA, 2 acres**ND**[CBI Deleted] -- McHenry County/Province, ND, 2 acres**SD**[CBI Deleted] -- Brookings County/Province, SD, USA, 2 acres**WA**[CBI Deleted] -- Whitman County/Province, WA, USA, 2 acres

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CBI-DELETED

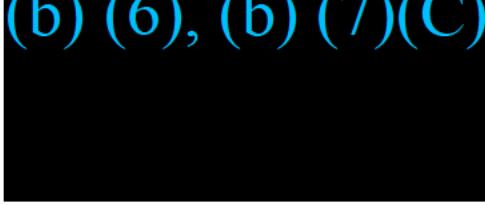
Monsanto Reference ID

2001-356XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 09, 2001

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CBI-DELETED

Monsanto Reference ID

2001-356XRAB

February 09, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-046-18n

1. USDA Reference Number

2. Applicant Reference Number 2001-356XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 11, 2001 - March 11, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-356XRAB

designation of transformed line:

33391

Constructs: PV-TXGT-10**GENE OF INTEREST***CBI*

Promoter: CMoVa/I2 -- [CBI Deleted]

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST*CBI*

Promoter: CMP3/I5 -- [CBI Deleted]

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

~~CBI DELETED~~

Monsanto Reference ID

2001-356XRAB

designation of transformed line:

TA_S2520

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

CBI

Terminator: M1 3' -- [CBI Deleted]

CBI DELETED

Monsanto Reference ID

2001-356XRAB

designation of transformed line:

TA_S9240

Constructs: PV-TXGT-17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-356XRAB

designation of transformed line:

TA_S7535, TA_S7890, TA_S9215

Constructs: PV-TXGT23**GENE OF INTEREST**Promoter: CMP3/15-2 -- [CBI Deleted]*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

~~CBI-DELETED~~

Monsanto Reference ID

2001-356XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 4,000 Kg. wheat seed to and from each location.

ORIGIN:

HI, IA, KS, MO, MT, ND, SD, WA

DESTINATION:

HI, IA, KS, MO, MT, ND, SD, WA

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

IA

[CBI Deleted] -- *Story County/Province, IA, U.S.A

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

~~CBI Deleted~~

Monsanto Reference ID

2001-356XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

ND

[CBI Deleted] -- *McHenry County/Province, ND

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA

~~CONFIDENTIAL~~

Monsanto Reference ID

2001-356XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

IA

[CBI Deleted] -- *Story County/Province, IA, U.S.A

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

~~CONFIDENTIAL~~

Monsanto Reference ID

2001-356XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

ND

[CBI Deleted] -- *McHenry County/Province, ND

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

~~CBI-DELETED~~

Monsanto Reference ID

2001-356XRAB

WA

[CBI Deleted] -- *Whitman County/Province, WA, USA

~~CBI-DELETED~~

Monsanto Reference ID

2001-356XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1), ND (1), SD (1), WA (1)-

MT

[CBI Deleted] -- Gallatin County/Province, MT, USA, 2 acres

ND

[CBI Deleted] -- McHenry County/Province, ND, 2 acres

SD

[CBI Deleted] -- Brookings County/Province, SD, USA, 2 acres

WA

[CBI Deleted] -- Whitman County/Province, WA, USA, 2 acres

MONSANTO

Food • Health • Hope



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-356XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 09, 2001

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

February 22, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-18n Applicant #: 2001-356XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI IA KS MO MT ND SD WA
Release destination: MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[Signature]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008237

file copy

Mr. Charles Stoltenow
IA Department of Agriculture and Land Stewardship
First Floor, Wallace building
East 9th Street and Grand Avenue
Des Moines, IA 50319

February 22, 2001

Dear Mr. Stoltenow:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-18n Applicant #: 2001-356XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI IA KS MO MT ND SD WA
Release destination: MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008238

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 22, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-18n Applicant #: 2001-356XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI IA KS MO MT ND SD WA
Release destination: MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008239

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 22, 2001

Dear Mr. Brown:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-18n Applicant #: 2001-356XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI IA KS MO MT ND SD WA
Release destination: MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|SJ|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008240

file copy

Ms. Mary Bryson, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 22, 2001

Dear Ms. Bryson:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-18n Applicant #: 2001-356XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI IA KS MO MT ND SD WA
Release destination: MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[Signature]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008241

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 22, 2001

Dear Mr. Nelson:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-18n Applicant #: 2001-356XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI IA KS MO MT ND SD WA
Release destination: MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008242

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 22, 2001

Dear Mr. Fridley:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-18n Applicant #: 2001-356XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI IA KS MO MT ND SD WA
Release destination: MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[Signature]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008243

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 22, 2001

Dear Mr. Wessels:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-18n Applicant #: 2001-356XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI IA KS MO MT ND SD WA
Release destination: MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008244

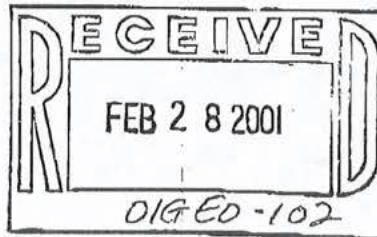


United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813



February 22, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-046-18n	Applicant #:	2001-356XRB
Received:	February 15, 2001	Effective:	March 17, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: HI IA KS MO MT ND SD WA			
Release destination: MT ND SD WA			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. Please notify Ms. Carol Okada Hawaii Dept. of Agriculture 701 Ilalo St., Honolulu, HI 96813.
 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. OKada

Signature: (b) (6), (b) (7)(C)

Date: 23 March 2001

State: Hawaii

Rptloc01/R4



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MAR 26 2001

OR120018_BR_008245



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Charles Stoltzenow
IA Department of Agriculture and Land Stewardship
First Floor, Wallace building
East 9th Street and Grand Avenue
Des Moines, IA 50319

February 22, 2001

Dear Mr. Stoltzenow:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-18n Applicant #: 2001-356XRAB
 Received: February 15, 2001 Effective: March 17, 2001
 Institution: Monsanto Recipient: Wheat
 Interstate destination: HI IA KS MO MT ND SD WA
 Release destination: MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
 Biotechnology Program Operations
 Permits and Risk Assessments
 Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: C. R. Stoltzenow

Signature: (b) (6), (b) (7)(C)

Date: March 12, 2001

State: Iowa

Rptloc01/R4



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AA Equal Opportunity Employer

MAR 12 2001

OR120018_BR_008246



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 22, 2001

Dear Mr. Brown:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-18n Applicant #: 2001-356XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI IA KS MO MT ND SD WA
Release destination: MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 3/6/01

State: MD

Rptloc01/R4

MAR 12 2001



APHIS - Protecting American Agriculture

OR120018_BR_008247



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Ms. Mary Bryson, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 22, 2001

Dear Ms. Bryson:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-18n Applicant #: 2001-356XRAB
 Received: February 15, 2001 Effective: March 17, 2001
 Institution: Monsanto Recipient: Wheat
 Interstate destination: HI IA KS MO MT ND SD WA
 Release destination: MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/28/01

State: Montana

Rptloc01/R4



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FEB 28 2001

OR120018_BR_008248



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 22, 2001

Dear Mr. Nelson:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number 01-046-18n Applicant #: 2001-356XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI IA KS MO MT ND SD WA
Release destination: MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,
(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Dave R. Nelson

Signature:

(b) (6), (b) (7)(C)

Date: 4-17-01

State: ND

Rptloc01/R4

*See attached
letter
conditions*



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

APR 18 2001

OR120018_BR_008249



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 22, 2001



Dear Mr. Fridley:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-18n Applicant #: 2001-356XRB
 Received: February 15, 2001 Effective: March 17, 2001
 Institution: Monsanto Recipient: Wheat
 Interstate destination: HI IA KS MO MT ND SD WA
 Release destination: MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
 Biotechnology Program Operations
 Permits and Risk Assessments
 Plant Protection and Quarantine

Enclosure

cc: R. Stroaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 3/01/01

State: South Dakota

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

MAR 5 2001

OR120018_BR_008250



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 22, 2001

Dear Mr. Wessels:

Enclosed is notification 01-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-046-18n	Applicant #:	2001-356XRAB
Received:	February 15, 2001	Effective:	March 17, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: HI IA KS MO MT ND SD WA			
Release destination: MT ND SD WA			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

 State concurs with APHIS determination.

 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 3/6/01

State: WA

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008251

MAR 6 2001

April 19, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 19, 2001.

Interstate movement and Release
Notification no. 01-046-18n (2001-356XRAB)
Regulated article - Wheat
Destinations - Hawaii, Iowa, Kansas, Missouri, Montana, North Dakota, South Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of North Dakota has (attached) supplemental conditions.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

OR120018_BR_008252

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
C. Stoltenow, Iowa Dept. of Agric. and Land Stewardship, Des Moines, IA
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Brown, Missouri Dept of Agric., Jefferson City, MO
L. Witham, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
T. Wessels, Washington Dept. of Agric., Olympia, WA
File number 01-046-18n

**AGRICULTURE COMMISSIONER
ROGER JOHNSON**



PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: James White
USDA-APHIS-PPQ
Biotechnology Risk Assessment
4700 River Road
Riverdale MD 20737

E. Diane Hatmaker
USDA-APHIS-PPQ
Permits-Biotechnology
4700 River Road
Riverdale MD 20737

FROM: David R. Nelson (b) (6), (b) (7)(C)

DATE: April 17, 2001

RE: Performance Standards for Wheat Notifications

We believe the performance standards for biotechnology wheat trials under notification or permit need to be strengthened to prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial. Standards should be stronger than those used for seed certification purposes because the needs of seed certification differ from the need to prevent persistence in the environment.

Biotechnology wheat trials planned for this and future growing seasons should incorporate the following safeguards:

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed. This distance reflects the pollen movement distances recognized by seed certification standards.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

CC

(b) (6), (b) (7)(C)

Confirmation Report-Memory Send

Time : Apr-19-01 05:19pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 687
Date : Apr-19 05:17pm
To : 916367377085
Document Pages : 03
Start time : Apr-19 05:17pm
End time : Apr-19 05:19pm
Pages sent : 03

Job number : 687 *** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

April 19, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 19, 2001.

Interstate movement and Release
Notification no. 01-046-18n (2001-356XRB)
Regulated article - Wheat

Destinations - Hawaii, Iowa, Kansas, Missouri, Montana, North Dakota, South Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of North Dakota has (attached) supplemental conditions.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure



APHIS - Protecting American Agriculture

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OR120018_BR_008255

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-046-18n **Monsanto #2001-356XRAB**

October 31, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147308221	Gallatin	MT
8014	McHenry	ND
2147303322	Brookings	SD
2147308358	Whitman	WA

Gallatin County/MT (2147308221)

(b) (4)

(b) (4)

McHenry County/ND (8014)

(b) (4)

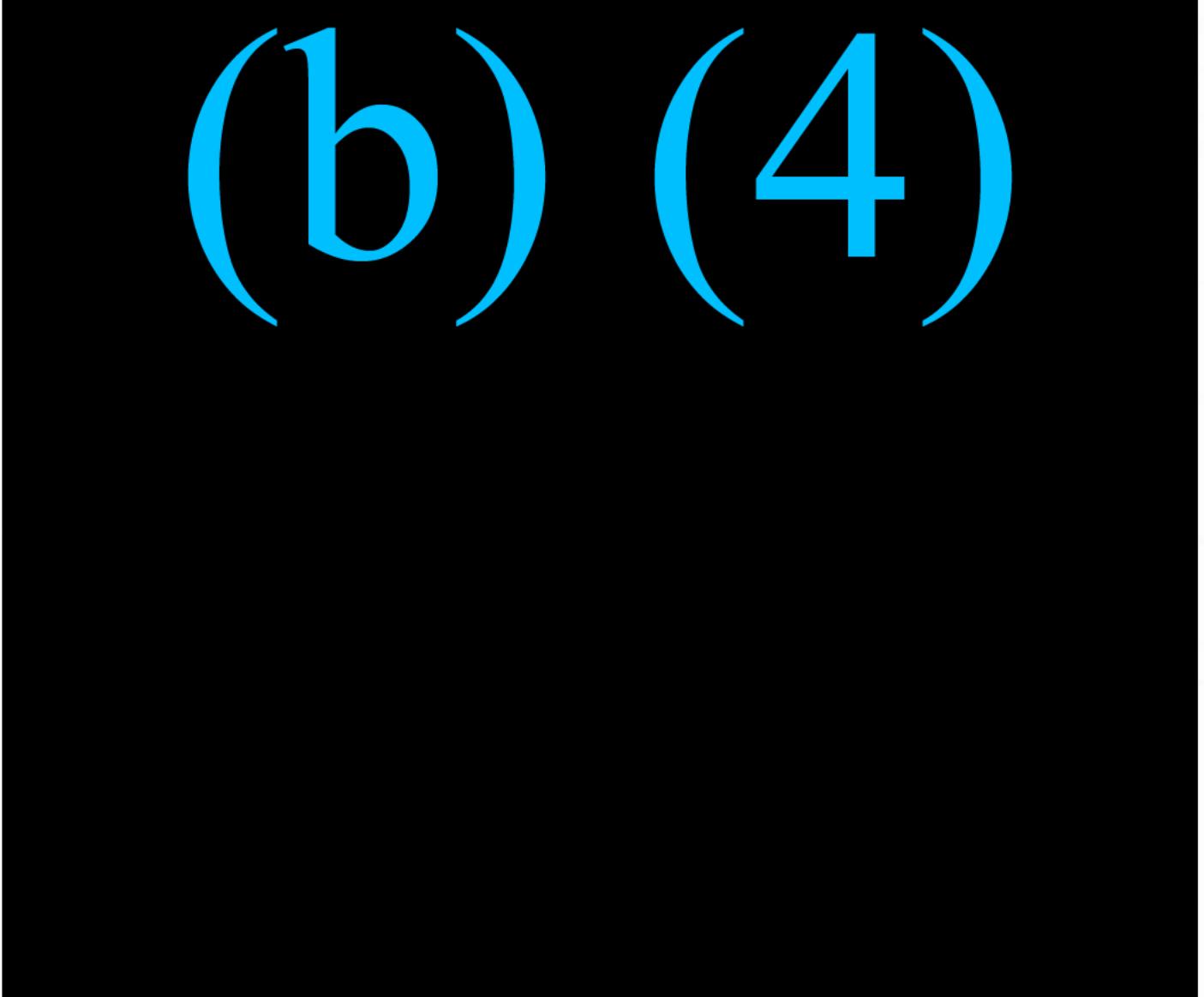
Brookings County/SI (2147303322)

(b) (4)

Whitman County/WA (2147308358)

(b) (4)

(b) (4)



CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2001 Wheat Field Test Report
USDA #01-046-18n **Monsanto #2001-356XRAB**

October 31, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147308221	Gallatin	MT
8014	McHenry	ND
2147303322	Brookings	SD
2147308358	Whitman	WA

Gallatin County/MT (2147308221)

Planting Date: 05/04/2001

Harvest Date: 09/03/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

McHenry County/ND (8014)

Planting Date: 05/11/2001

Harvest Date: 08/20/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Brookings County/SD (2147303322)

Planting Date: 05/17/2001

Harvest Date: 08/27/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Whitman County/WA (2147308358)

Planting Date: 04/25/2001

Harvest Date: 09/01/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

=====
 Bp number: 01-046-19n
 =====

App number: 2001-357XRAB Begin movement: 3/11/01
 Received: 2/15/01 End movement: 3/11/02
 Institution: Monsanto Begin release: 3/11/01
 Recipient: Wheat End release: 3/11/02
 Status: Pending Acre: 5.00
 Effective date: 3/17/01 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: [REDACTED] (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

		Initial	Date
1.	[<input checked="" type="checkbox"/>] Assign Bp number and initial data entry	[apd]	[2/22/01]
2.	[<input checked="" type="checkbox"/>] Review by biotechnologist	[suik]*	[2/23/01]*
3.	[<input checked="" type="checkbox"/>] Letter of notification to State Fed-ex	[KRL]	[2/27/01]*
4.	[<input type="checkbox"/>] State response		

O/d	Loc	Site	Reg		
Interstate	*Dest*HI	*	*WR *	[]	[]
Interstate	*Dest*KS	*	*SCR *	[]	[]
Interstate	*Dest*MN	*	*NER *	[]	[]
Interstate	*Dest*MO	*	*SCR *	[]	[]
Interstate	*Orig*HI	*	*WR *	[]	[]
Interstate	*Orig*KS	*	*SCR *	[]	[]
Interstate	*Orig*MN	*	*NER *	[]	[]
Interstate	*Orig*MO	*	*SCR *	[]	[]
Release	*	*MN	*	[]	[]

5.	[<input checked="" type="checkbox"/>] Enter genes into database	[apd]	[2/23/01]
6.	[<input checked="" type="checkbox"/>] Letter of acknowledgement/denial/withdraw	[KRL]	[4/23/01]*
7.	[<input checked="" type="checkbox"/>] Enter final data into database	[KRL]	[4/25/01]
8.	[<input type="checkbox"/>] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

Reason for tardiness: (MN) responded on 4/23/2001.

MONSANTO

Food • Health • Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-357XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 09, 2001

01-046-19n

1. USDA Reference Number

2. Applicant Reference Number 2001-357XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North
St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 11, 2001 - March 11, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2001-357XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [REDACTED]

(b) (4) [REDACTED]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- [REDACTED]

(b) (4) [REDACTED]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-357XRAB

7. Mode of Transformation Disarmed *Agrobacterium tumefaciens*

8. Introduction Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN:

DESTINATION:

Ship From:

HI

*[REDACTED] (b) (4) Honolulu
County/Province, HI. (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A(b) (4), (b) (6), (b) (7)(C)
1 - CBI

KS

*[REDACTED] (b) (4) Sedgwick County/Province, KS, (b) (4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)
] - CBI

MN

*[REDACTED] (b) (4) Polk County/Province,
MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

Comments: (b) (4), (b) (6), (b) (7)(C)]-
CBI

CONFIDENTIAL

Monsanto Reference ID

2001-357XRAB

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A] - CBI
CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C)
] - CBI

Ship To:

HI

*[(b) (4) Honolulu
County/Province, HI, (b) (4) U.S.A.
CONTACT: (b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C)
] - CBI

KS

*[(b) (4) Sedgwick County/Province, KS (b) (4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,
] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-357XRAB

MN

*[(b) (4) Polk County/Province,
MN (b) (4) USA] -

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (5), (b) (6), (b) (7)(B) U.S.A., (b) (4), (b) (6), (b) (7)(C)

Comments: CBI

(b) (4)

] -

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A] -

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (5), (b) (6), (b) (7)(B) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-357XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1)

MN

(b) (4)

Polk County/Province, MN,

USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

Comments: (b) (4)] -
CBI

MONSANTO

Food · Health · Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-357XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 09, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

MONSANTO

Food · Health · Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-357XRAB

Permit Unit

February 09, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-046-19n

1. USDA Reference Number

2. Applicant Reference Number 2001-357XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North
St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 11, 2001 - March 11, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-357XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-357XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MN, MO

DESTINATION:

HI, KS, MN, MO

Ship From:**HI**[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.**KS**[CBI Deleted] -- *Sedgwick County/Province, KS, USA**MN**[CBI Deleted] -- *Polk County/Province, MN, USA

CBI-DELETED

Monsanto Reference ID

2001-357XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

Ship To:**HI**

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Polk County/Province, MN, USA

CBI-DELETED

Monsanto Reference ID
2001-357XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID
2001-357XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1)

MN

[CBI Deleted] -- Polk County/Province, MN, USA, 5 acres

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

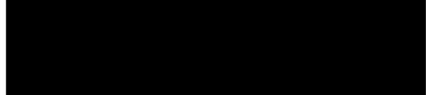
Monsanto Reference ID

2001-357XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 09, 2001

MONSANTO

Food • Health • Hope



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBP-DELETED

Monsanto Reference ID

2001-357XRAB

February 09, 2001

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-046-19n

1. USDA Reference Number

2. Applicant Reference Number 2001-357XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North
St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release

March 11, 2001 - March 11, 2002

5. Recipient

Wheat, *Triticum aestivum*

6. Regulated Article

Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2001-357XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

~~CONFIDENTIAL~~

Monsanto Reference ID

2001-357XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 3000 pounds of wheat seed to and from each location.

ORIGIN:

HI, KS, MN, MO

DESTINATION:

HI, KS, MN, MO

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Polk County/Province, MN, USA

~~CONFIDENTIAL~~

Monsanto Reference ID

2001-357XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MN

[CBI Deleted] -- *Polk County/Province, MN, USA

~~CONFIDENTIAL~~

Monsanto Reference ID

2001-357XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

Monsanto Reference ID

2001-357XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1)

MN

[CBI Deleted] -- Polk County/Province, MN, USA, 5 acres

MONSANTO

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MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

OPTIONAL FORM

Monsanto Reference ID

2001-357XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

[Redacted area]

Monsanto Company

February 09, 2001

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

February 22, 2001

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-046-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-19n Applicant #: 2001-357XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MN MO
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008291

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 22, 2001

Dear Mr. Sim IV:

Enclosed is notification 01-046-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-19n Applicant #: 2001-357XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MN MO
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008292

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 22, 2001

Dear Dr. Hanks:

Enclosed is notification 01-046-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-19n Applicant #: 2001-357XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MN MO
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008293

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 22, 2001

Dear Mr. Brown:

Enclosed is notification 01-046-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-19n Applicant #: 2001-357XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MN MO
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[S]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

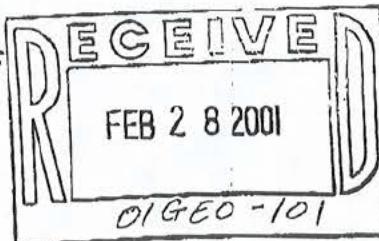


United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813



February 22, 2001 ~

Dear Mr. Isherwood Jr.:

Enclosed is notification 01-046-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-19n Applicant #: 2001-357KRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MN MO
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. Please notify Ms. Carol Okada Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol T. Okada

Signature: (b) (6), (b) (7)(C)

Date: 23 March 2001

State: Hawaii

Rptloc01/R4



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MAR 26 2001

OR120018_BR_008295



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

01- NOV-01

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 22, 2001 ~

Dear Dr. Hanks:

Enclosed is notification 01-046-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-19n Applicant #: 2001-357XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MN MO
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. *with the attached conditions*

 State DOES NOT CONCUR and offers the following reasons:

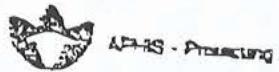
Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 4-24-01

State: MN

Rptloc01/R4



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An Equal Opportunity Employer

APR 23 2001

OR120018_BR_008296



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 22, 2001 ~

Dear Mr. Brown:

Enclosed is notification 01-046-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number 01-046-19n Applicant #: 2001-357XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: HI KS MN MO
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Michael E. Brown

Signature:

(b) (6), (b) (7)(C)

Date: 3/6/01

State: MO

Rptloc01/R4

MAR 12 2001



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

April 23, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 23, 2001.

Interstate movement and Release

Notification no. 01-046-19n (2001-357XRAB)

Regulated article - Wheat

Destinations - Hawaii, Kansas, Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota has (attached) supplemental conditions.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

OR120018_BR_008298

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept of Agric., Jefferson City, MO
File number 01-046-19n



Minnesota Department of Agriculture (651) 296-1277

April 24, 2001

Ms. Mary Jackson
Biotechnology Program Operations
Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

Fax: 301-734-8910

RE: Additional Conditions for Release of Wheat 01-046-19n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat plants appearing within this area should be destroyed.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Blanks, Ph.D.
State Biotechnologist

Confirmation Report-Memory Send

Time : Apr-24-01 05:09pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 757
Date : Apr-24 05:07pm
To : 916367377085
Document Pages : 03
Start time : Apr-24 05:07pm
End time : Apr-24 05:09pm
Pages sent : 03
Job number : 757

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

(b) (6), (b) (7)(C)

April 23, 2001

700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to
7 CFR 340.3(c), effective on or after April 23, 2001.

Interstate movement and Release
Notification no. 01-046-19n (2001-357XRAB)
Regulated article - Wheat

Destinations - Hawaii, Kansas, Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota has (attached) supplemental conditions.
In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii, 96813 upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_008301

CONFIDENTIAL

**2001 Wheat Field Test Report
USDA #01-046-19n Monsanto #2001-357XRB**

October 2, 2002

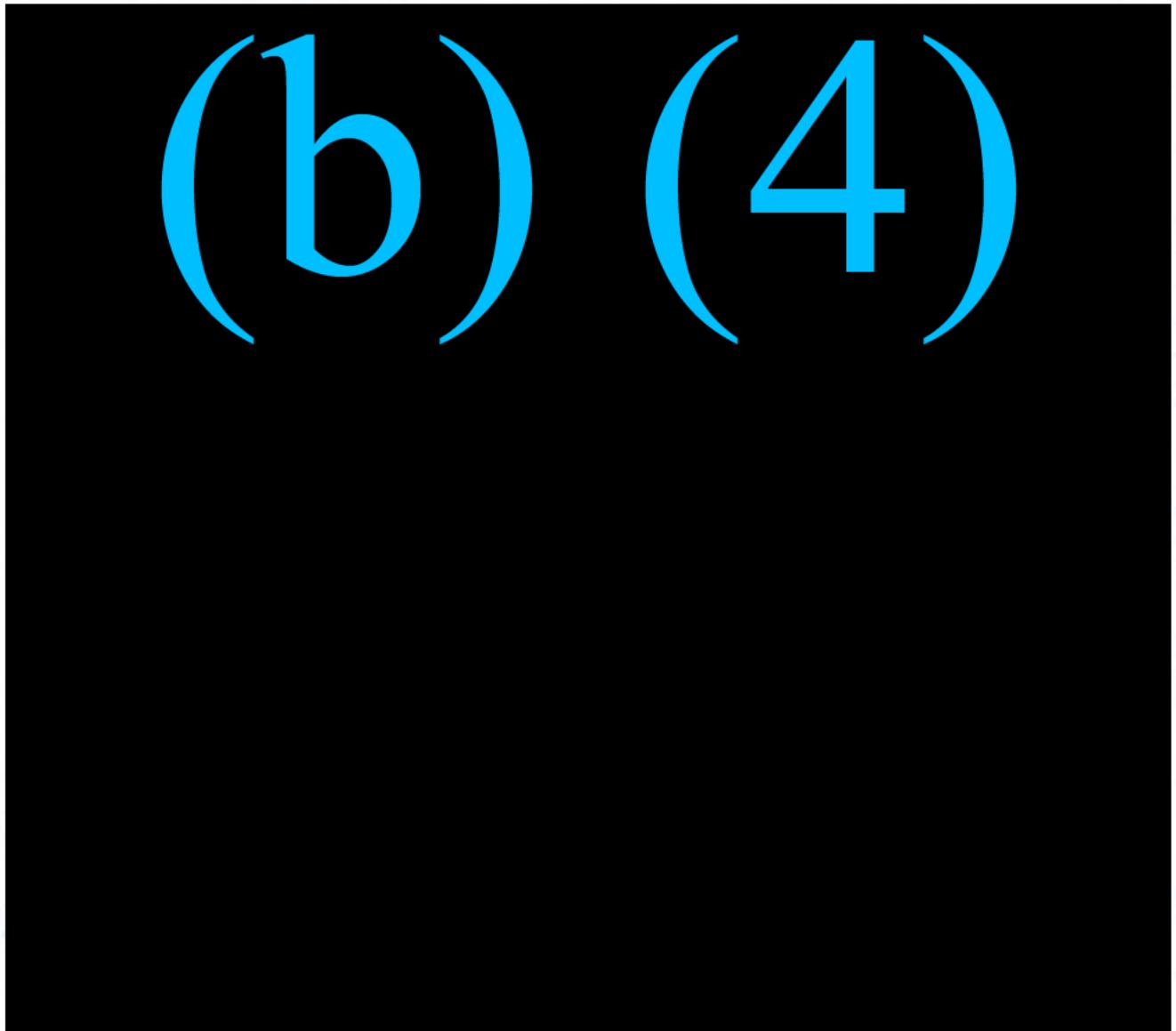
**Biotech Field Compliance Team
Monsanto Company**

Location
2147303429

County
Polk County

State
MN

Polk County/MN (2147303429)



CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-046-19n Monsanto #2001-357XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

Location	County	State
2147303429	Polk County	MN

Polk County/MN (2147303429)

Planting Date: 05/14/2001

Harvest Date: 08/07/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily OR 120016_BR_008304

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

=====
 Bp number: 01-046-20n
 =====

App number: 2001-362XRAB Begin movement: 3/15/01
 Received: 2/15/01 End movement: 3/15/02
 Institution: Monsanto Begin release: 3/15/01
 Recipient: Wheat End release: 3/15/02
 Status: Pending Acre: 20.00
 Effective date: 3/17/01 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: [REDACTED] (b) (6), (b) (7)(C)
 Parsed name: [REDACTED]
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085
 =====

		Initial	Date
1.	[<input checked="" type="checkbox"/> Assign Bp number and initial data entry	[apd]	[2/22/01]
2.	[<input checked="" type="checkbox"/> Review by biotechnologist	[tMK]*	[2/23/01]*
3.	[<input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KLD]	[2/27/01]*
4.	[<input type="checkbox"/> State response		

O/d	Loc	Site	Reg		
Interstate	*Dest*MO	*	*SCR	*	[] []
Interstate	*Dest*WA	*	*WR	*	[] []
Interstate	*Orig*MO	*	*SCR	*	[] []
Interstate	*Orig*WA	*	*WR	*	[] []
Release	*	*WA	*	1*WR	*
5.	[<input checked="" type="checkbox"/> Enter genes into database	[apd]	[2/23/01]		
6.	[<input checked="" type="checkbox"/> Letter of acknowledgement denial/withdraw	[KLD]	[3/15/01]*		
7.	[<input checked="" type="checkbox"/> Enter final data into database	[KLD]	[3/16/01]		
8.	[<input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify				

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MONSANTO COMPANY

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CHESTERFIELD, MISSOURI 63198
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FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-362XRAB

Permit Unit

February 13, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-046-20n

1. USDA Reference Number

2. Applicant Reference Number 2001-362XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North
St. Louis MO 63198

Phone (b) (6), (b) (7)(C)
FAX 636/737-7085
EMail (b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

March 15, 2001 - March 15, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2001-362XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [REDACTED]

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [REDACTED]

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-362XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 70,000 pounds of wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From:**MO***[(b) (4)] St. Louis County/Province, MO, (b) (4)
U.S.ACONTACT: (b) (4), (b) (6), (b) (7)(C)
MO, (b) (4), (b) (6), (b) (7)(C)
] - CBI**WA***(b) (4) Grant County/Province, WA, (b) (4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4) USA,
(b) (4), (b) (6), (b) (7)(C)
] - CBI**Ship To:****MO***[(b) (4)] St. Louis County/Province, MO, (b) (4)
U.S.A

CONFIDENTIAL

Monsanto Reference ID

2001-362XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)
MO [REDACTED] U.S.A, (b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

*[(b) (4) Grant County/Province, WA, (b) (4) USA
CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-362XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4)

Grant County/Province, WA, USA, 20 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

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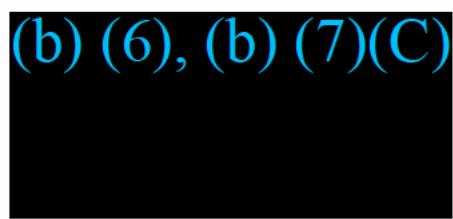
Monsanto Reference ID

2001-362XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 13, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

Monsanto Reference ID

2001-362XRAB

Permit Unit

February 13, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-046-20n

1. USDA Reference Number

2. Applicant Reference Number 2001-362XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 15, 2001 - March 15, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2001-362XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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CBI-DELETED

Monsanto Reference ID

2001-362XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 70,000 pounds of wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From:**MO**[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A**WA**[CBI Deleted] -- *Grant County/Province, WA, USA**Ship To:****MO**[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID
2001-362XRAB

WA

[CBI Deleted] -- *Grant County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-362XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

[CBI Deleted] -- Grant County/Province, WA, USA, 20 acres

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9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 13, 2001

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4700 River Rd.

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February 13, 2001

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1. USDA Reference Number

2. Applicant Reference Number 2001-362XRAB

3. Applicant/Responsible Party

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Monsanto Company

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St. Louis

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4. Duration of Introduction

Interstate Movement and Release

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5. Recipient

Wheat, Triticum aestivum

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Phenotypic Category:

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Phenotype:

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CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

~~CBI-DELETED~~

Monsanto Reference ID

2001-362XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 70,000 pounds of wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

WA

[CBI Deleted] -- *Grant County/Province, WA, USA

Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

~~CONFIDENTIAL~~

Monsanto Reference ID

2001-362XRAB

WA

[CBI Deleted] -- *Grant County/Province, WA, USA

MONSANTO

Food • Health • Hope



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-362XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 13, 2001

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 22, 2001

Dear Mr. Brown:

Enclosed is notification 01-046-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-20n Applicant #: 2001-362XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: MO WA
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008328

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 22, 2001

Dear Mr. Wessels:

Enclosed is notification 01-046-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-046-20n	Applicant #:	2001-362XRAB
Received:	February 15, 2001	Effective:	March 17, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008329



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

--Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 22, 2001

Dear Mr. Brown:

Enclosed is notification 01-046-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-20n Applicant #: 2001-362XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: MO WA
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Michael E. Brown

Signature:

(b) (6), (b) (7)(C)

Date: 3/6/01

State: MO

Rptloc01/R4

MAR 12 2001



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OR120018_BR_008330



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 22, 2001

Dear Mr. Wessels:

Enclosed is notification 01-046-20n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	01-046-20n	Applicant #:	2001-362XRAB
Received:	February 15, 2001	Effective:	March 17, 2001
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: MO WA			
Release destination: WA			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (a) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Thomas L. Wessels
Signature: (b) (6), (b) (7)(C)

Date: 3/6/01

State: WA

Rptloc01/R4



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OR120018_BR_008331

MAR 6 2001

March 15, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 17, 2001.

Interstate movement and Release
Notification no. 01-046-20n (2001-362XRAB)
Regulated article - Wheat
Destinations - Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

CC:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
S. Wood, PPQ, ER, Raleigh, NC
File number 01-046-20n

OR120018_BR_008332

Confirmation Report-Memory Send

Time : Mar-16-01 12:07pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 906
Date : Mar-16 12:00pm
To : 916367377085
Document Pages : 01
Start time : Mar-16 12:00pm
End time : Mar-16 12:06pm
Pages sent : 01

Job number : 906 *** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 15, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to
7 CFR 340.3(c), effective on or after March 17, 2001.

Interstate movement and Release
Notification no. 01-046-20n (2001-362XRAB)
Regulated article - Wheat
Destinations - Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You
or any of your cooperators who will be involved in handling the regulated article
must be prepared with a written or verbal description of the methods to be
employed to meet each performance standard. In addition, all packages must be
clearly labeled as to content, and notification number must be prominently
displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field
test.

A copy of this letter of acknowledgment will be sent to the receiving State
Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

CC:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
S. Wood, PPQ, ER, Raleigh, NC



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OR120018_BR_008333

CONFIDENTIAL

**2001 Wheat Field Test Report
USDA #01-046-20n Monsanto #2001-362XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

Location

519

County

Grant County

State

WA

Grant County/WA (519)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-046-20n Monsanto #2001-362XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
519	Grant County	WA

Grant County/WA (519)

Planting Date: 04/12/2001

Harvest Date: 08/13/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

=====
 Bp number: 01-046-21n
 =====

App number:	2001-363XRAB	Begin movement:	3/15/01
Received:	2/15/01	End movement:	3/15/02
Institution:	Monsanto	Begin release:	3/15/01
Recipient:	Wheat	End release:	3/15/02
Status:	Pending	Acre:	2.00
Effective date:	3/17/01	CBI status:	CBI
Phenotype:	HT - Glyphosate tolerant		
Comments:			
Resp person:	(b) (6), (b) (7)(C)		
Parsed name:			
Address1:	Monsanto Company		
Address2:	700 Chesterfield Parkway N.		
Address3:			
Address4:			
City/State/Zip:	Chesterfield, MO 63198		
Telephone:	(b) (6), (b) (7)(C)	Fax:	636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[<i>ajd</i>]	[<i>2/22/01</i>]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[<i>RJR</i>]*	[<i>02/23/01</i>]*
3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i>	[<i>KLnD</i>]	[<i>2/27/01</i>]*
4. <input type="checkbox"/> State response		

O/d	Loc	Site	Reg		
Interstate	*Dest*MO	*	*SCR	*	[] []
Interstate	*Dest*WA	*	*WR	*	[] []
Interstate	*Orig*MO	*	*SCR	*	[] []
Interstate	*Orig*WA	*	*WR	*	[] []
Release	*	*WA	*	1*WR	*
5. <input checked="" type="checkbox"/> Enter genes into database					[<i>ajd</i>] [<i>2/27/01</i>]
6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw					[<i>KLnD</i>] [<i>3/15/01</i>]*
7. <input checked="" type="checkbox"/> Enter final data into database					[<i>KLnD</i>] [<i>3/16/01</i>]
8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify					

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-363XRAB

Permit Unit

February 13, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-046-21n

1. USDA Reference Number

2. Applicant Reference Number 2001-363XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North
St. Louis MO 63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

March 15, 2001 - March 15, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite, BW251, HJ-98 & Westbred 926

CONFIDENTIAL

Monsanto Reference ID

2001-363XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [REDACTED]

(b) (4)

CBI

[REDACTED]
(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- [REDACTED]

(b) (4)

CBI

[REDACTED]
(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2001-363XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 2,000 pounds of wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From:

MO

*[REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
MO, [REDACTED] U.S.A, (b) (4), (b) (6), (b) (7)(C)
] - CBI

WA

*[REDACTED] (b) (4) Grant County/Province, WA, (b) (4), USA
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) WA, [REDACTED] USA,
(b) (4), (b) (6), (b) (7)(C)
] - CBI

Ship To:

MO

*[REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONFIDENTIAL

Monsanto Reference ID

2001-363XRAB

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
MO [REDACTED] U.S.A, (b) (4), (b) (6), (b) (7)(C)

] - CBI

WA

*[REDACTED] (b) (4) Grant County/Province, WA (b) (4) USA
CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) WA, [REDACTED] (b) (4) USA,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2001-363XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

(b) (4)

Grant County/Province, WA, USA, 2 acres.

RESPONSIBLE PERSON/RESEARCHER:
(b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

Food • Health • Hope



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63108
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2001-363XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 13, 2001

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

CBI Justification
Notification 2001-363XRAB
Page 3

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-363XRAB

Permit Unit

February 13, 2001

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

01-046-21n

1. USDA Reference Number

2. Applicant Reference Number 2001-363XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)
FAX 636/737-7085
EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North
St. Louis MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 15, 2001 - March 15, 2002

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite, BW251, HJ-98 & Westibred 926

CBI-DELETED

Monsanto Reference ID

2001-363XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2001-363XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

Ship up to 2,000 pounds of wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

WA

[CBI Deleted] -- *Grant County/Province, WA, USA**Ship To:**

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

CBI-DELETED

Monsanto Reference ID
2001-363XRAB

WA

[CBI Deleted] -- *Grant County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2001-363XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

[CBI Deleted] -- Grant County/Province, WA, USA, 2 acres

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-363XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 13, 2001

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MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63108
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CBI-DELETED

Monsanto Reference ID

2001-363XRAB

February 13, 2001

Permit Unit

USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

01-046-21n

1. USDA Reference Number
2. Applicant Reference Number 2001-363XRAB
3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release ✓ March 15, 2001 - March 15, 2002

5. Recipient

Wheat, Triticum aestivum✓

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant ✓

Cultivar/Variety Bobwhite, BW251, HJ-98 & Westbred 926

~~CBI DELETED~~

Monsanto Reference ID

2001-363XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

~~CBI-DELETED~~

Monsanto Reference ID

2001-363XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 2,000 pounds of wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

WA

[CBI Deleted] -- *Grant County/Province, WA, USA

Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

~~CONFIDENTIAL~~

Monsanto Reference ID
2001-363XRAB

WA

[CBI Deleted] -- *Grant County/Province, WA, USA

CBI DELETED

Monsanto Reference ID

2001-363XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA (1)

WA

[CBI Deleted] -- Grant County/Province, WA, USA, 2 acres

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700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63108
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

CBI-DELETED

Monsanto Reference ID

2001-363XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 13, 2001

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 22, 2001

Dear Mr. Brown:

Enclosed is notification 01-046-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-21n Applicant #: 2001-363XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: MO WA
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[SJ]

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008362

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 22, 2001

Dear Mr. Wessels:

Enclosed is notification 01-046-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-21n Applicant #: 2001-363XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: MO WA
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

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Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_008363



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 22, 2001 ~

Dear Mr. Brown:

Enclosed is notification 01-046-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-21n Applicant #: 2001-363XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: MO WA
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 3/6/01

State: MO

Rptloc01/R4

MAR 12 2001



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OR120018_BR_000001



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

February 22, 2001

Dear Mr. Wessels:

Enclosed is notification 01-046-21n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 01-046-21n Applicant #: 2001-363XRAB
Received: February 15, 2001 Effective: March 17, 2001
Institution: Monsanto Recipient: Wheat
Interstate destination: MO WA
Release destination: WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (a) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 3/6/01

State: WA

Rptloc01/R4



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MAR 6 2001

OR120018_BR_008365

March 15, 2001

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 17, 2001.

Interstate movement and Release
Notification no. 01-046-21n (2001-363XRAB)
Regulated article - Wheat
Destinations - Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
S. Wood, PPQ, ER, Raleigh, NC
File number 01-046-21n

OR120018_BR_008366

Confirmation Report-Memory Send

Time : Mar-16-01 12:07pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 907
Date : Mar-16 12:02pm
To : 916367377085
Document Pages : 01
Start time : Mar-16 12:02pm
End time : Mar-16 12:07pm
Pages sent : 01
Job number : 907

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 15, 2001

(b) (6), (b) (7)(C)

MONSANTO COMPANY
700 Chesterfield Parkway N
St. Louis, MO 63196

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 17, 2001.

Interstate movement and Release
Notification no. 01-046-2ln (2001-363XRAB)
Regulated article - Wheat
Destinations - Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

CC:
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
R. Stoaks, PPQ, WR, Sacramento, CA
S. Wood, PPQ, ER, Raleigh, NC



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OR120018_BR_008367

CONFIDENTIAL

2001 Wheat Field Test Report
USDA #01-046-21n Monsanto #2001-363XRAB

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

Location

519

County

Grant County

State

WA

Grant County/WA (519)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2001 Wheat Field Test Report
USDA #01-046-21n Monsanto #2001-363XRAB**

October 2, 2002

**Biotech Field Compliance Team
Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
519	Grant County	WA

Grant County/WA (519)

Planting Date: 04/12/2001

Harvest Date: 08/09/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the harvested material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]